PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 23 January 2001 (23.01.01)	
International application No. PCT/IL00/00269	**Applicant's or agent's file reference** 11037/WO/00
International filing date (day/month/year) 11 May 2000 (11.05.00)	**Priority date** (day/month/year) 11 May 1999 (11.05.99)
Applicant IZILOV, Ahi-Izil et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

07 December 2000 (07.12.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. E. Stoffel

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
11037/WO/00		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IL 00/00269	11/05/2000	11/05/1999
Applicant		
S.I.N.A.I. MEDICAL TECHNOLOGIES LTD.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2a

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/IL 00/00269

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/74 A61B17/86 A61B17/72 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02105 A (BRAMLET DALE G) 22 January 1998 (1998-01-22) page 13, line 27 -page 14, line 11 page 15, line 6 - line 21 figures 2,5,6	1,2,4,5, 7,10,12, 14,15, 25,36,58
A	CH 475 754 A (PAUL KLEUSER CHIRURGISCHE INSTRUMENTE UND APPARATE) 31 July 1969 (1969-07-31) column 2, line 17 - line 33; figure 1	1,2,4,5, 7,21,36, 58
A	EP 0 636 346 A (SANTANGELO MASSIMO) 1 February 1995 (1995-02-01) the whole document	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 September 2000	26/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ducreau, F

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]T/IL 00/00269

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 437 674 A (KOVACS ERIC ET AL) 1 August 1995 (1995-08-01) column 3, line 26 - line 65; figure 1	1,2,4,5, 7,58
A	US 4 432 358 A (FIXEL IRVING E) 21 February 1984 (1984-02-21) figures 1,2	1-5,8
A	US 4 236 512 A (AGINSKY JACOB) 2 December 1980 (1980-12-02) claim 1; figure 1	1,21,25, 58
A	FR 2 653 660 A (HECHARD PATRICK) 3 May 1991 (1991-05-03) claim 1; figure 5	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 00/00269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802105 A	22-01-1998	US 5976139 A	02-11-1999
		AU 3662597 A	09-02-1998
		EP 0925038 A	30-06-1999
CH 475754 A	31-07-1969	NONE	
EP 0636346 A	01-02-1995	JP 7067897 A	14-03-1995
		US 5534004 A	09-07-1996
		US 5759184 A	02-06-1998
US 5437674 A	01-08-1995	FR 2695026 A	04-03-1994
		AT 182063 T	15-07-1999
		AU 670456 B	18-07-1996
		AU 4963893 A	15-03-1994
		BR 9305618 A	02-01-1996
		CA 2122017 A	03-03-1994
		DE 69325642 D	19-08-1999
		DE 69325642 T	06-04-2000
		EP 0609425 A	10-08-1994
		ES 2136666 T	01-12-1999
		WO 9404086 A	03-03-1994
		HU 67894 A,B	29-05-1995
		JP 7500520 T	19-01-1995
		NO 941487 A	22-04-1994
US 4432358 A	21-02-1984	NONE	
US 4236512 A	02-12-1980	NONE	
FR 2653660 A	03-05-1991	FR 2626169 A	28-07-1989

PATENT COOPERATION TREATY

PCT

REC'D 13 FEB 2001

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
11037/WO/00		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00269	11/05/2000	11/05/1999
International Patent Classification (IPC) or national classification and IPC A61B17/74		
Applicant S.I.N.A.I. MEDICAL TECHNOLOGIES LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07/12/2000	09.02.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Weber, P Telephone No. +49 89 2399 2873

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00269

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-56 as originally filed

Claims, No.:

1-58 as originally filed

Drawings, sheets:

1/21-21/21 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 58.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 58 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-57

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-57
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-57
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

see Item VIII.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. A device according to the preamble of Claim 1 is known from D1(SU-A-938969):

The device according to Claim 1 differs from the one disclosed in D1 in that the antimigration device comprises axially movable fixation means for selectively setting and fixing the relative axial position of the gripping means with respect to the second cylinder.

This additional constructional feature allows an anchorage of the screw member in the bone were desired, increasing the versatility and universatility of the device.

The combination of features of claim 1 is not suggested by the cited documents.

For this reasons Claim 1 fulfils the requirements of Art.33(2)(3) PCT.

2. The dependent Claims 2 to 57 are concerned with improvements of the device according to Claim 1, so that they also fulfil the requirements of Art.33(2)(3) PCT.

3. Industrial applicability is self-evident, so that Claims 1-57 also meet the requirements of Art.33(4) PCT.

VII

Certain defects in the international application

1. The features of the claims are not provided with reference signs placed in

parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

1. The subject-matter of Claim 58 is unclear contrary to Art.6 PCT, the technical features of the device defined in this claim are not clear. A reference to the drawings is not considered to be a clear definition of the device since it is impossible to know which features shown in the drawings are meant.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
11037/WO/00		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00269	11/05/2000	11/05/1999
International Patent Classification (IPC) or national classification and IPC A61B17/74		
Applicant S.I.N.A.I. MEDICAL TECHNOLOGIES LTD. et al.		

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   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
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   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07/12/2000	09.02.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Weber, P Telephone No. +49 89 2399 2873

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00269

I. Basis of the report

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Claims, No.:

1-58 as originally filed

Drawings, sheets:

1/21-21/21 as originally filed

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- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

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- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

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- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

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☐ the entire international application.

☒ claims Nos. 58.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 58 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-57

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-57
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-57
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

see Item VIII.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. A device according to the preamble of Claim 1 is known from D1(SU-A-938969):

The device according to Claim 1 differs from the one disclosed in D1 in that the antimigration device comprises axially movable fixation means for selectively setting and fixing the relative axial position of the gripping means with respect to the second cylinder.

This additional constructional feature allows an anchorage of the screw member in the bone were desired, increasing the versatility and universatility of the device.

The combination of features of claim 1 is not suggested by the cited documents.

For this reasons Claim 1 fulfils the requirements of Art.33(2)(3) PCT.

2. The dependent Claims 2 to 57 are concerned with improvements of the device according to Claim 1, so that they also fulfil the requirements of Art.33(2)(3) PCT.

3. Industrial applicability is self-evident, so that Claims 1-57 also meet the requirements of Art.33(4) PCT.

Certain defects in the international application

1. The features of the claims are not provided with reference signs placed in

parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

1. The subject-matter of Claim 58 is unclear contrary to Art.6 PCT, the technical features of the device defined in this claim are not clear. A reference to the drawings is not considered to be a clear definition of the device since it is impossible to know which features shown in the drawings are meant.

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61B 17/74, 17/86, 17/72, 17/80

A1

(11) International Publication Number: WO 00/67653

(43) International Publication Date: 16 November 2000 (16.11.00)

(21) International Application Number: PCT/IL00/00269

(22) International Filing Date: 11 May 2000 (11.05.00)

(30) Priority Data:

129903	11 May 1999 (11.05.99)	IL
132742	4 November 1999 (04.11.99)	IL

(71) Applicant *(for all designated States except US)*: S.I.N.A.I. MEDICAL TECHNOLOGIES LTD. [IL/IL]; 64 Hashahar Street, 43565 Raanana (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: IZILOV, Ahi–Izil [IL/IL]; 58–b Derech Tsarfat, 35437 Haifa (IL). NICKELSHPUR, Gennady [IL/IL]; 9–d Habastilia Street, 35597 Haifa (IL). AHARONSON, Zeev [IL/IL]; 22 Yehuda Halevi Street, 43556 Raanana (IL).

(74) Agents: LUZZATTO, Kfir et al.; Luzzatto & Luzzatto, P.O. Box 5352, 84152 Beer–Sheva (IL).

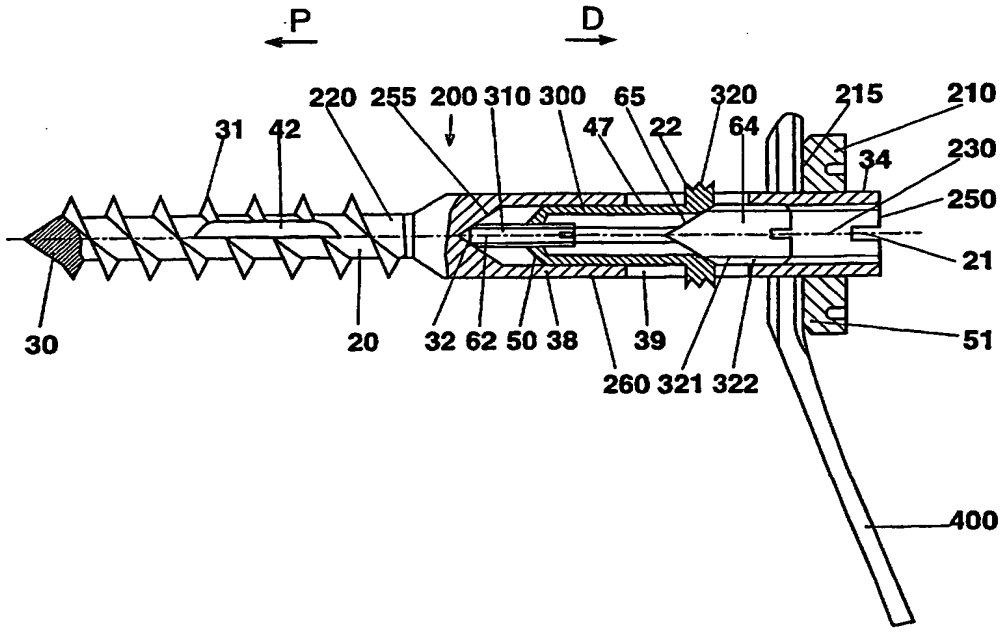
(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: UNIVERSAL HIP COMPRESSION DEVICE



(57) Abstract

A universal osteosynthesis device for fixating femur fractures, the device being in the form of a screw member having a proximal screw thread for compressingly engaging within the femur under axial load provided by a compression nut applied to the distal end of the screw member. The screw member includes an axially shiftable migration device which opens when it is desired to anchor the device within the femur. Extension members are provided further enabling the device to be used with a large range of patients. A locking plate is provided which can be quickly and easily adapted to the particular features of a patient's femur.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
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INTERNATIONAL SEARCH REPORT

[redacted]tional Application No
PCT/IL 00/00269

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/74 A61B17/86 A61B17/72 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02105 A (BRAMLET DALE G) 22 January 1998 (1998-01-22) page 13, line 27 -page 14, line 11 page 15, line 6 - line 21 figures 2,5,6	1,2,4,5, 7,10,12, 14,15, 25,36,58
A	CH 475 754 A (PAUL KLEUSER CHIRURGISCHE INSTRUMENTE UND APPARATE) 31 July 1969 (1969-07-31) column 2, line 17 - line 33; figure 1	1,2,4,5, 7,21,36, 58
A	EP 0 636 346 A (SANTANGELO MASSIMO) 1 February 1995 (1995-02-01) the whole document	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 September 2000	26/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ducreau, F

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 00/00269

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 437 674 A (KOVACS ERIC ET AL) 1 August 1995 (1995-08-01) column 3, line 26 - line 65; figure 1	1,2,4,5, 7,58
A	US 4 432 358 A (FIXEL IRVING E) 21 February 1984 (1984-02-21) figures 1,2	1-5,8
A	US 4 236 512 A (AGINSKY JACOB) 2 December 1980 (1980-12-02) claim 1; figure 1	1,21,25, 58
A	FR 2 653 660 A (HECHARD PATRICK) 3 May 1991 (1991-05-03) claim 1; figure 5	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 00/00269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802105 A	22-01-1998	US 5976139 A	02-11-1999
		AU 3662597 A	09-02-1998
		EP 0925038 A	30-06-1999
CH 475754 A	31-07-1969	NONE	
EP 0636346 A	01-02-1995	JP 7067897 A	14-03-1995
		US 5534004 A	09-07-1996
		US 5759184 A	02-06-1998
US 5437674 A	01-08-1995	FR 2695026 A	04-03-1994
		AT 182063 T	15-07-1999
		AU 670456 B	18-07-1996
		AU 4963893 A	15-03-1994
		BR 9305618 A	02-01-1996
		CA 2122017 A	03-03-1994
		DE 69325642 D	19-08-1999
		DE 69325642 T	06-04-2000
		EP 0609425 A	10-08-1994
		ES 2136666 T	01-12-1999
		WO 9404086 A	03-03-1994
		HU 67894 A,B	29-05-1995
		JP 7500520 T	19-01-1995
		NO 941487 A	22-04-1994
US 4432358 A	21-02-1984	NONE	
US 4236512 A	02-12-1980	NONE	
FR 2653660 A	03-05-1991	FR 2626169 A	28-07-1989

UNIVERSAL HIP COMPRESSION DEVICE

Technical Field

The present invention relates to a device for fixating a fractured femur by holding together in compression the fractured portions of the femur. In particular the present invention relates to a universal fixating device that may be adapted to take account of anatomical as well as physiological differences between a range of patients.

Background

Referring to Figure 1, the general anatomical regions of interest of the femur (1) include the capest or femur head (2), collum or femur neck (3), the Trochanter major (4), Trochanter minor (5), Undertrochanter area (6), Cortical layer (7) and Diafiz (8).

In the present specification, the term proximal (P) refers to a direction towards and into the patient body, while the term distal (D) refers to a direction generally away from the patient body. Thus, referring to Figure 1, the femur may be divided for easy reference into a proximal area and distal area.

Referring again to Figure 1, femur neck fractures may be divided into medial fractures and lateral fractures. Medial fractures include subcapital fractures (9), transcervical fractures (10) and basal fractures (11). Lateral fractures include

transtrochanter fractures (12), intertrochanter fractures (13) and undertrochanter fractures (14).

Broken lines (15), (16), (17) and (18) schematically illustrate the dimensional relationship between the distal and proximal areas of the femur in different patients. Line (19) represents a reference axis of the femur neck (3).

The problem of treating femur neck fractures is of great social importance, especially in geriatrics, such fractures occurring more commonly with the elderly than with other age groups. Such fractures are often caused, particularly after age 70, by a relatively light trauma, non-coordinated movements, sharp turns, walking, going upstairs, lifting and carrying heavy loads, as due to senile osteoporosis characteristic of elderly people, wherein the bones become more brittle and fragile. Unfortunately femur neck fractures, especially subcapital fractures, often knit badly, so that for elderly people they often become a fatal injury.

In the USA alone, medical statistics estimate 250 thousand femur neck fractures annually. 20% of victims die within a year. After a year' treatment 15-20% of patients are still in need of care, with 50% of them suffering from aftereffects. $ 7 billions are annually spent in USA to provide medical care of patients with femur neck fractures (H.W. Wahner, 1987).

The vast majority of elderly people with femur neck fractures have different susceptibility to aging and may also suffer from a number of debilitating diseases. They also tend to have limited reserves as well as less effective immune systems. Even after correct and timely osteosynthesis with elderly and old people, nonunion of femur neck fractures and development of femur head necrosis occurs nearly in 30 % of patients (A.V.Kaplan, 1979).

Most of patients in this age group suffer from pronounced osteoporosis. Therefore stops such as femur screws or nails are badly fixed in a porous bone. This often results in a second displacement and nonunion of bone fragments. With patients in this age group subcapital femur neck fractures occur most frequently, and fragments fixing at osteoporosis appears to be inadequately stable. Therefore medical practice has been to treat femur neck fractures of elderly people with the use of an endoprosthesis. Total replacement of the thigh joint in such patients is carried out very seldom because of its traumatability, hemophilia as well as of osteoporosis and essential operational risk. Endoprosthesis at femur neck fractures is performed more often though there is a great number of contraindications to its application. It would not be correct to apply it at all femur neck fractures in elderly patients.

Closed osteosynthesis by means of a special device to treat such fractures appears to be the most favourable course of action for elderly patients. Even in cases where fracture non-union eventually occurs, it can still provide at least short-term relief to patients.

A number of devices have been proposed for closed osteosynthesis of femur neck fractures, such as Richards compression screw system by "Richards Manufacturing Co. Inc.", Memphis, Tennessee, USA, (U.S. Pat. No. 4,095,591, the contents of which are included herein by reference thereto).

The compression screw system includes an extension provided for being nonrotatably fixed to a lag screw that is to be anchored to the head of a femur or other bone in a manner so as to allow compression to be applied to a fracture. The extension extends outward of the bone when attached to the lag screw is anchored to the bone to allow a compression plate to be easily

positioned thereof. The cross section of the extension is substantially the same as the cross section of the lag screw to allow the compression plate to be easily and quickly passed onto the lag screw from the extension once the compression plate has been positioned on the extension.

The Richards system has a number of drawbacks, as follows: a) the bone tissue of the femur head is drilled out over the whole duct length whereby bone tissue (trabeculae) and endosteum is essentially destroyed, and the blood supply which is already insufficient is affected; b) the design of the introduced rod and its inadequately effective thread do not provide a stable compression connection of bone parts. At best bone fragments simply come in contact without a stable mutual fixation. Micromobility of bone fragments is as well possible. c) to position Richards system it is necessary to make a large cut in the femur muscular tissues to locate a compression plate. Thus, the Richards system is inadequate to the task of treating femur neck fractures, especially of subcapital fractures which simply do not knit in most cases.

Since the publication of U.S. Pat. No. 4,095,591 numerous improvements of Richards system have been attempted as described in, for example, U.S. Patent Nos. 4,236,512; 4,432,358; 4,791,918; 4,794,919; 4,964,403; 5,871,485 (1978-1999), Patent of Israel No. 54025 (1978), the contents of which are included herein by reference thereto.

However all the above mentioned devices have similar drawbacks to the Richards system- high traumatability of the femur bone and tissues and inadequate efficiency for the treatment of femur neck fractures, such as medial

fractures. The application of the devices disclosed by these patents for the treatment of subcapital fractures is simply unsuitable.

There are also known devices developed by "Howmedica International Inc." (U.S. Pat. No. 5, 176, 681), "Smith & Nephew Richards Inc." (U.S. Pat. No. 5, 167, 663 and EP 0441577), "Endocare AG" (U.S. Pat. No. 5, 713, 902). The contents of these references are included herein by reference thereto. These devices comprise a rod introduced inside the hip bone and a screw attached to this rod to fix the femur neck. The devices are unwieldy, may cause traumas to the patient, and their efficacy is on the level of the Richard system device (do not provide a stable compression connection of bone parts).

There is further known an "Osteosynthesis device" disclosed in U.S. Pat. No. 5,437,674, the contents of which are included herein by reference thereto. An osteosynthesis device including a screw whose tip is pyramidal or conical and whose body is provided, at a distal end thereof, with an outside thread, wherein the head of the screw has a plurality of foldable small wings integral with the body and wherein the screw has a device for folding the small wings. The device is useful particularly for fractures of the scaphoid, of the medial malleolus, Garden fractures 1 and 2 of the neck of the femur, pertrochanterian fractures of the femur, and generally, for fractures of small bones, and for putting in place hip or shoulder stops.

However this device is also inadequately efficient for the treatment of femur neck fractures, such as medial fractures. It cannot be used for the treatment of subcapital fractures.

In SU 938969, the contents of which are included herein by reference thereto, an osteosynthesis device for femur neck fractures is disclosed. The device comprises a rod with a buttress thread on one end and a hold-down nut on the other end of the rod having an internal thread. There are also provided tabs located in apertures formed in the rod on the side of the hold-down nut and a mechanism for operating the tabs. The mechanism includes a screw disposed in the inner tread of the rod and engaging the tabs.

However this device also has some drawbacks. It is not universal as its design does not allow for the differences in linear femur neck dimensions with different people, different cortical layer thickness in the undertrochanter femur area. Furthermore, the tabs are fixed axially with respect to the rod, and moreover do not enable the anchoring in the bone to be sufficiently secure. Therefore such a device must be manufactured individually for each patient or in series differing in dimensions according to anthropological parameters of different patients, so that the axial length of the rod, as well as the precise location of the tabs with respect thereto (and therefore to the optimal part of the bony tissue in which the tabs should be anchored) may be optimised for each patient.

Furthermore, the device of SU 938969 is unsuitable for treating some types of lateral fractures, such as undertrochanter fractures, and therefore unsuitable as a universal hip compression device for all kinds of femur neck fractures.

Many prior art devices use a rigid pressure or locking plate for supporting a femur screw or nail member that is introduced in the femur. Such prior art pressure plates are rigidly mounted to the screw member at the distal end thereof at a particular angle, and the plate itself is then mounted to the femur with the aid of a number of nails or wood screws, for example, driven through

the plate and into the femur, well below the diafiz. Since the angle between the plate and the screw member is fixed, the pressure plate must usually be mounted to the femur first, and then the screw member implanted into the femur neck. As such, depending on the particular type of fractures as well as anatomical details of each patient, the angle between these components must be determined before surgery, and a special pressure plate/screw member combination for the patient must be provided in which the angle is irreversibly set. A great disadvantage of this type of system is that the angle in which the screw member must be implanted into the femur must be matched to the angle required by the pressure plate, otherwise unwanted stresses are introduced into the femur.

An object of the present invention is to provide a universal and simple device for compression treatment of all kinds of femur neck fractures including medial fractures and including both subcapital fractures and lateral fractures, such as undertrochanter, intertrochanter and transtrochanter fractures.

Another object of the present invention is to provide a device for the fixation of femur fractures comprising means for reliably anchoring the device in the bone with all types of femur neck fractures.

It is another object of the present invention to provide a device for the fixation of femur fractures enabling the reliable compressive union of bone parts in patients with different anthropometric dimensions of femur neck.

Another object of the present invention is to provide a fixation device which reduces traumatization of a patient's bones and tissues during implantation of the device.

It is another object of the present invention to provide a universal pressure

plate for use with a screw member, either that disclosed herein or indeed with any other suitable screw member, in which the angle between the screw member and the pressure plate may be adjusted and set during the implantation procedure.

It is another object of the present invention to provide such a fixation device that is simple to use.

It is another object of the present invention to provide such a fixation device that is relatively simple mechanically and thus economic to produce as well as to maintain in comparison to prior art devices.

The present invention achieves these and other objects by providing a device for fixating a fractured femur in which thrust surfaces of a screw thread at the proximal end of a screw member together with a compression member to bring together in compression parts of the fractured femur. An axially movable and settable antimigration device anchors the screw member in the bone where desired, increasing the versatility and universality of the device. Extension members increase the effective axial length of the screw member to take account of anatomical differences between patients.

Further, a two-part pressure plate is provided for use with any suitable screw member, in particular the fixating device of the present invention. In the two-part pressure or locking plate, one part is adapted for mounting with respect to the screw member, and the other part is adapted for mounting to the femur, and is characterised in that the linear and/or angular relationship between the two parts may be adjusted as required, particularly in situ.

Summary of Invention

The present invention relates to a device for fixating a fractured femur, comprising :-

(a) an elongated screw member adapted for penetrating into at least the neck portion of a femur, comprising :-

a proximal portion comprising a first cylindrical member having an external first screw thread adapted for distal compressive engagement with bony tissue in particular within the femur;

a distal portion comprising a second cylindrical member having an internal cavity and a substantially open distal end, and at least one lateral portal for enabling communication between said cavity and an outside of said second cylindrical member;

an antimigration device accommodated in said cavity and comprising at least one anchoring means having gripping means, said at least one anchoring means being selectively extendable in a substantially lateral direction such that said gripping means extends to said outside of said distal portion via a corresponding one of said at least one portal, said gripping means being adapted for anchoring said antimigration device within bony tissue when said gripping means is brought into compressive engagement therewith;

and

(b) compression means releasably engageable with said distal portion of said screw member and selectively axially displaceable with respect thereto, said compression means having a proximal pressure face for selectively compressively engaging proximally with a distal end of said femur either directly or via any suitable washer interface such as a locking plate;

and is characterised in that said antimigration device comprises axially movable fixation means for selectively setting and fixing the relative axial position of said gripping means with respect to said second cylindrical member.

In the preferred embodiment, said first cylindrical member is integrally joined to said second cylindrical member, and said first screw thread comprises an external diameter substantially similar to an external diameter of said second cylindrical member. Further, said first cylindrical member comprises and axial lumen extending therethrough and having a proximal opening in said first cylindrical member and in communication with said cavity, said axial lumen and said cavity being of a size sufficient to enable a suitable alignment needle to be accommodated therein. Preferably, at least the proximal end of said first screw thread is self-taping with respect to bony tissue, and optionally said at least proximal end of said screw thread comprises a plurality of circumferentially spaced radial slots to provide portions of said screw thread in the form of blade-like elements separated by said radial slots, said blade like elements having leading edges adapted for taping into bony tissue.

In the preferred embodiment, said first screw thread comprises at least distal thread surfaces adapted for compressive engagement with bony tissue in response to a distal longitudinal force applied to said screw member. The said distal thread surfaces of said first screw thread preferably comprise a distal tilt angle of between about 2° to about 4°., and said first screw thread further comprises proximal thread surfaces having a proximal tilt angle of between about 30° to about 35°.

Optionally, said proximal portion of said screw member comprises at least one longitudinal groove for facilitating transportation of bony tissue debris from the

proximal end to the distal end of said first cylindrical member during implantation of said device.

In the preferred embodiment, said at least one portal is in the form of a longitudinal slit along the cylindrical wall of said second cylindrical member, and said antimigration device comprises a proximally disposed ring, substantially coaxial with said second cylindrical member, and wherein said at least one anchoring means is in the form of a corresponding resilient arm cantilevered from said ring and extending substantially distally therefrom, said arm having a corresponding said at least one gripping means at the free distal end thereof, said antimigration device further comprising actuation means for reversibly extending said gripping means in a lateral direction . The actuation means may comprise an axially movable thrust element having an external second screw thread complementary to and engaged with an internal third screw thread comprised at least in a distal portion of said cavity of said second cylindrical member, wherein a proximal end of said thrust element comprises a convex conical surface, said conical surface adapted to abut against and urge said free end of said at least one arm laterally outwards in response to an axial translation in the proximal direction by said thrust element. The thrust element may comprise a substantially diametrical slot on the distal end thereof for engaging with an external complementary first tool so as to enable said thrust member to be axially displaced within said cavity by means of corresponding rotation of said first tool. The gripping means may comprise an externally facing tab having at least one bone-engaging edge, preferably said bone-engaging edge being serrated. In the preferred embodiment, said at least one arm is biased such that said tab does not significantly protrude from said corresponding at least one portal when said actuation means is disengaged from said anchoring means.

The axially movable fixation means for selectively setting and fixing the relative axial position of said gripping means with respect to said second cylindrical member may comprise a stub member engaged with and axially movable with respect to said ring member, said stub member having a proximal end for rotatably abutting against a proximal end of said cavity, and a distal end axially spaced from said engagement means. The stub member may comprise an external fourth screw thread complementary to and engaged with an internal fifth screw thread comprised in said second ring member, and the distal end of said stub member may also comprise a substantially diametrical slot for engaging with an external complementary second tool so as to enable said ring member to be axially displaced respect to said stub member by means of corresponding rotation of said second tool.

In the preferred embodiment, the said compression means comprises an axially movable first nut element having an internal sixth screw thread complementary to and engaged with an external seventh screw thread comprised at least in a distal portion of said second cylindrical member, and a proximal end of said first nut element preferably comprises a rounded annular edge. Advantageously, said first nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said screw member by means of corresponding rotation of said third tool.

In the first embodiment of the device the second cylindrical member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said screw member to be axially advanced into a femur by means of corresponding rotation of said fourth tool.

The preferred embodiment of the device optionally further comprises an axially engageable longitudinal extension member for effectively increasing the axial length of said screw member, wherein at least a proximal portion of said extension member comprises an external second screw thread complementary to and engaged with an internal third screw thread comprised at least in a distal portion of said cavity of said second cylindrical member, and wherein said compression means is releasably engageable with a distal portion of said extension member and selectively axially displaceable with respect thereto. Said extension member may be a tubular member having an external diameter substantially complementary to the internal diameter of said distal end of said screw member, and the said compression means comprises an axially movable second nut element having an internal eighth screw thread complementary to and engaged with said external second screw thread comprised in a distal portion of said extension member, the proximal end of said second nut element preferably comprising a rounded annular edge. Further, said second nut element advantageously comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary fifth tool so as to enable said second nut element to be axially displaced within with respect to said extension member by means of corresponding rotation of said fifth tool. Also, such an extension member preferably comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary sixth tool so as to enable said extension member to be axially displaced with respect to said screw member by means of corresponding rotation of said sixth tool.

Alternatively, said extension member may be a stepped tubular member having a proximal portion and a distal portion, wherein said proximal portion of said tubular member comprises an external diameter substantially complementary to

the internal diameter of said distal end of said screw member, and wherein said distal portion of said tubular member comprises an external diameter substantially equal to the external diameter of said distal end of said screw member. With such an extension member, the compression means comprises an axially movable first nut element having an internal sixth screw thread complementary to and engaged with an external seventh screw thread comprised in at least a distal portion of said extension member, the proximal end of said second nut element preferably comprising a rounded annular edge. Further, said first nut element may comprise a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said extension member by means of corresponding rotation of said third tool. Also, the extension member may comprise a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said extension member to be axially displaced with respect to said screw member by means of corresponding rotation of said fourth tool.

The present invention also relates to a pressure plate for securing a femur nail or screw to a femur, used in fixating a fractured femur. While being novel per se, the pressure plate of the present invention is particularly useful in conjunction with the fixating device of the present invention. The pressure plate of the present invention is characterised in having an upper plate portion, a lower plate portion and adjusting means for adjusting at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion, and wherein said upper plate portion is adapted for rigid securement to said screw member (or to any suitable femur screw or nail) via said compression means, and wherein said

lower plate portion is adapted for rigid securement with respect to a distal portion of the femur. The lower plate portion preferably comprises a proximal surface having a profile complementary to a lower portion of said distal portion of the femur, and may be rigidly secured to said distal portion of said femur by at least one suitable screw via a corresponding at least one aperture comprised in said lower plate portion. The upper plate portion preferably comprises a proximal surface having a profile complementary to an upper portion of said distal portion of the femur, and comprises a first aperture adapted for securingly engaging with a distal end of said device, and wherein said compression means compressively engages proximally with a distal end of said femur via said upper plate portion. When used with other femur screws or nails instead of the device of the present invention, the said upper plate portion is adapted for securement to the distal end of the femur screw or nail in a similar manner, mutatis mutandis. The pressure plate further comprises fixing means for fixing at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion.

When said compression means for the device is in the form of a nut member having a rounded proximal annular edge, said first aperture may have a flared distal entry complementary shaped to said rounded proximal annular edge.

In a first embodiment of the pressure plate, the adjustment means comprises a hinge arrangement having a first hinge element comprised at an upper end of said lower plate portion and a cooperating second hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, said upper end of said upper plate portion comprising said first aperture and said lower end of said upper plate portion comprising said fixing means. In this embodiment, the fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial

displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion, said threaded portion having a proximal end rotatably engaged with said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

In a second embodiment of the pressure plate, the adjustment means comprises a linearly adjustable hinge arrangement having a first male hinge element comprised at an upper end of said lower plate portion and a cooperating second female hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, said upper end of said upper plate portion comprising said first aperture and said lower end of said upper plate portion comprising said fixing means, wherein said female hinge element comprises a plurality of lateral apertures for selectively articulatingly engaging said male element in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin. In this embodiment, the fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion, said threaded portion having a proximal end for abutting against a distal surface of said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

In a third embodiment of the pressure plate, the adjustment means comprises a linearly adjustable hinge arrangement having a first male hinge element comprised at an upper end of said lower plate portion and a cooperating

second female hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, wherein said female hinge element comprises a plurality of lateral apertures for selectively articulatingly engaging said male element in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin, wherein said upper end of said upper plate portion comprises at least one said first aperture, and wherein said lower end of said upper plate portion comprises at least one said second aperture, said fixing means being associated with any one of said at least one second aperture. In this embodiment, the upper plate portion may be selectively engaged with respect to the said lower plate portion in one of a first or a second orientation corresponding to having said upper end or said lower end respectively, of said upper plate portion uppermost, wherein said at least one second apertures are substantially identical to said at least one first apertures, and wherein in said second orientation, one said second aperture is associated with said device and one said first aperture is associated with said fixing means. Further in this embodiment, the fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to complementary threaded said second aperture comprised in said lower end or in said upper end of said upper plate portion, when said upper plate element is in said first or said second orientation, respectively, said threaded portion having a proximal end for abutting against a distal surface of said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means. Preferably, said upper plate portion has a substantially S-shaped transverse cross-section.

In a fourth embodiment of the pressure plate, the adjustment means is in the form of a curved lower end comprised in said upper plate portion, said slot having laterally disposed shoulders parallel thereto and cooperating with a male reaction block comprised an upper end of said lower plate portion, wherein said curved lower end and said block comprising suitable profiles such as to enable the area of contact between said lower end and said block to be adjusted such as to provide at least one of a range of relative angular dispositions and a range of relative linear displacements between said upper plate portion and said lower plate portion. In this embodiment, the fixing means comprises at least one screw device for clamping said upper plate portion to said lower plate portion, said at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded third aperture comprised in said block of said lower plate portion, and wherein said at least one screw device further comprises a thrust surface for clamping contact with a distal surface of said lower portion, and an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said lower plate portion by suitable means. The fixing means preferably comprises two said screw devices disposed along the length of said block, and the slot preferably has an open lower end.

The present invention also relates to methods for fixating a fractured femur, using the device of the present invention, optionally with one or more extension members.

The present invention also relates to methods for fixating a fractured femur using the pressure plate of the present invention together with the device of the present invention, or alternatively with any other suitable femur screw or nail device.

Description of Figures

Figure 1 shows in side elevational cross-sectional view, the general anatomical areas of interest of a human femur.

Figure 2 shows a preferred embodiment of the present invention:-Figure 2(a):- in side elevational partial cross-sectional view; Figure 2(b):- a variation of proximal end of the embodiment in side elevational partial cross-sectional view; Figure 2(c):- the embodiment of Figure 2(b) viewed along Q-Q; Figure 2(d):- the pressure plate of Figure 2(a) in perspective view; Figure 2(e):-a transverse perspective view of Figure 2(d) along A-A; Figure 2(f):-a transverse perspective view of Figure 2(d) along B-B.

Figure 3 shows in side elevational cross-sectional view one embodiment of an extension member.

Figure 4 shows in side elevational partial cross-sectional view, the embodiment of Figure 2 having a modified tip and comprising the extension member of Figure 3.

Figure 5 shows in side elevational cross-sectional view detail (II) of screw thread portion of the embodiment of Figure 4.

Figure 6 shows in side elevational partial cross-sectional view, the distal part of the embodiment of Figure 2 having a comprising an alternative extension member.

Figure 7 shows in perspective view a first embodiment of the locking plate according to the present invention.

Figure 8 shows in plan view the embodiment of Figure 7.

Figure 9 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 8 taken along C-C.

Figure 10 shows in perspective view the lower plate portion of the embodiment of Figure 7.

Figure 11 shows in cross-section the embodiment of Figure 8 taken along D-D.

Figure 12 shows in cross-section the embodiment of Figure 9 taken along E-E.

Figure 13 shows in perspective view a second embodiment of the locking plate according to the present invention.

Figure 14 shows in plan view the embodiment of Figure 13.

Figure 15 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 14 taken along F-F.

Figure 16 shows in perspective view the lower plate portion of the embodiment of Figure 13.

Figure 17 shows in cross-section the embodiment of Figure 14 taken along G-G.

Figure 18 shows in cross-section the embodiment of Figure 15 taken along H-H.

Figure 19 shows in perspective view a third embodiment of the locking plate according to the present invention.

Figure 20 shows in plan view the embodiment of Figure 19.

Figure 21 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 20 taken along J-J.

Figure 22 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 20.

Figure 23 shows in cross-section the embodiment of Figure 20 taken along K-K.

Figure 24 shows in cross-section the embodiment of Figure 20 taken along L-L.

Figure 25 shows in perspective view a fourth embodiment of the locking plate according to the present invention.

Figure 26 shows a rear view of the upper plate portion of the embodiment of Figure 25 in the direction (III).

Figure 27 shows in plan view the embodiment of Figure 25.

Figure 28 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 27 taken along M-M.

Figure 29 shows in perspective view the lower plate portion of the embodiment of Figure 25.

Figure 30 shows in cross-section the embodiment of Figure 27 taken along N-N.

Figure 31 shows in cross-section the embodiment of Figure 27 taken along O-O.

Figure 32 shows in side elevational partial cross-sectional view a first drill used for boring into the femur.

Figure 33 shows in side elevational partial cross-sectional view a second drill used for boring into the femur.

Figure 34 shows in side elevational view a third drill used for boring into the femur.

Figure 35 shows in side elevational partial cross-sectional view a screw holder engaged with the embodiment of Figure 2(a) having a lumen.

Figure 36 shows in side elevational partial cross-sectional view a proximal portion of the screw holder of Figure 35.

Figure 37 shows in side elevational partial cross-sectional view a special screw wrench engaged with the embodiment of Figure 2(a) having a lumen.

Figure 38 shows in cross-sectional view the embodiment of Figure 37 taken along C-C.

Figure 39 shows in side elevational partial cross-sectional view a proximal portion of the special screw wrench of Figure 37.

Figure 40 shows in side elevational partial cross-sectional view a nut holder engaged with the embodiment of Figure 2(a) having a lumen.

Figure 41 shows in side elevational partial cross-sectional view a proximal portion of the nut holder of Figure 40.

Figure 42 shows in side elevational partial cross-sectional view an all-purpose wrench.

Figure 43 shows in side elevational view an additional element for use in conjunction with the all-purpose wrench of Figure 42.

Figure 44 illustrates schematically the lumens required to be bored into the femur for implantation of the embodiments of Figures 1 to 6.

Figure 45 illustrates schematically a part of the implantation procedure for the embodiments of Figures 1 to 6 using the screw holder of Figures 35 and 36.

Figure 46 illustrates schematically a part of the implantation procedure for the embodiments of Figures 1 to 6 using the special screw wrench of Figures 37 to 39.

Figure 47 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur.

Figure 48 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 7 to 12.

Figure 49 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 13 to 18.

Figure 50 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 19 to 24.

Figure 51 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 25 to 31

Disclosure of Invention

The present invention is defined by the claims, the contents of which are to be read as included within the disclosure of the specification, and will now be described by way of example with reference to the accompanying Figures.

In the present specification, the term "distal" (D) refers to a direction away from the trunk or body of the patient, while the term "proximal" (P) refers to a direction towards the trunk or body of the patient. Thus, referring to Figure 1, the femur head (2) is proximal with respect to the trochanter major (4).

The present invention relates to a device for fixating a fractured femur, in particular for holding in compression parts of a fractured femur neck. Referring to the Figures, Figures 2(a), 2(b) and 2(c) illustrate a preferred embodiment of the present invention. The device, designated by the numeral (200), comprises a screw member (20) and a compression means (210) releasably engageable with a distal portion of the screw member (20), and an axially settable antimigration device (300).

The screw member (20) comprises a proximal portion comprising a first cylindrical member (220) having a screw thread (31) along its outer surface. The screw thread (31) is adapted for compressive engagement with bony tissue, particularly bony tissue within the femur, in response to a longitudinal force applied distally to the screw member (20), i.e., along the central longitudinal axis (230) thereof. Accordingly, and referring to Figure 5, the screw thread (31) advantageously has a buttress-like transverse cross-sectional profile, in which the distally-facing thread surfaces (44) are approximately perpendicular to the longitudinal axis (230), while the proximally facing thread surfaces (43) is at an acute angle to this axis (230). Preferably, the distal thread surfaces (44) comprise a distal tilt angle β of between about 2° to about 4°, and

the proximal thread surfaces (43) comprise a proximal tilt angle α of between about 30° and about 35°, said tilt angles being measured from a radial line perpendicular to the axis (230). This type of profile for the screw thread (31) reduces resistance from the bony tissue when helically advancing the device (200) in the proximal direction, while at the same time maximising the axial thrust resistance in the distal direction. Such high distal resistance (achieved together with action of compression means (210)) is advanatgeous in promoting compressive union of the fractured parts of the bone The screw thread (31), in particular the proximal end thereof, is preferably self-tapping, minimising trauma in the bone during the insertion procedure which is thereby simplified. Preferably, and referring in particular to Figures 2(b) and 2(c), the proximal end of the screw thread (31) comprises a plurality of - in these figures, three - radial slots (235), thereby forming the remaining portions of the screw thread (31) separated by the slots (235) into blade-like elements (240) having radial leading edges (245). Said leading edges (245) are particularly sharpened and are thus well suited to facilitate the self-taping action of the screw thread (31) into the bony tissue. Typically, the ratio between the outer diameter and the inner diameter of the screw thread (31) is about 3:2. Further typically, the screw thread (31) is integral with the said first cylindrical member (220).

Optionally, at least a proximal portion, and preferably the whole length of the first cylindrical member (220) further comprises at least one or a plurality, and optimally two or three, longitudinal grooves (42). The grooves (42) provide channels for bone debris formed during the tapping operation of the screw member (220) into the bone to be removed from the immediate vicinity of the screw thread (31) and thereby prevent premature clogging and jamming of the

screw member (220), which could restrict advancement of the screw member (220) into the femur and/or cause deterioration of the fracture .

The said first cylindrical member (220) may be solid, having a conical tip (30), as illustrated in Figure 2(a). Alternatively, the first cylindrical member (220) may comprises an axial lumen (29) extending therethrough and having an opening (40) in a truncated tip (30'), as illustrated in Figure 4. This lumen (29) is of a diameter sufficient to enable a suitable alignment needle to be accommodated therein, as described hereinbelow.

The screw member (20) further comprises a distal portion comprising a second cylindrical member (260) having an internal cavity (35) and a substantially open distal end (250). The second cylindrical member (260) is of a larger external diameter than the first cylindrical member (220), being typically approximately equal to the outer diameter of the screw thread (31). This geometry enables the first cylindrical member (220) to be proximally advanced into a distal part of the femur that is bored to accommodate the second cylindrical member (260). Thus, the size of the screw thread (31) is on the one hand maximised, while on the other hand providing stability and close fit of the second cylindrical member (260) within the bore provided for it at the distal end of the femur. Typically, the said first cylindrical member (220) is integrally joined to the second cylindrical member (260). The said second cylindrical member (260) also comprises a pair of substantially diametrically opposed radial slots (21) on the distal end thereof for engaging with an external complementary tool. The slots (21) enable the screw member (20) to be axially advanced into the femur by means of engagement of this tool with the slots (21), and rotation of the tool, which causes the screw member (20) to rotate and for the screw thread (31) to engage and penetrate into the femur, as will be further described hereinbelow.

The cavity (35) is in communication with the lumen (29) when the latter is formed in said first cylindrical member, and the cavity (35) is of a size at least sufficient to enable said alignment needle to be accommodated therein. Typically, though, the cavity (35) is much wider, and comprises a proximal wall (255) at the proximal end thereof, which may be in the form of a concave cone typically having truncated or pointed apex, depending on whether or not the first cylindrical member comprises a lumen (29), respectively.

The second cylindrical member (260) further comprises at least one lateral portal for enabling communication between the cavity (35) and the outside of the second cylindrical member (260). Typically about three such portals are provided, advantageously in the form of longitudinal slots (39) in the cylindrical wall (38) of the said second cylindrical member (260).

The compression means (210) are releasably engageable with a distal portion of the screw member (20) and is selectively axially displaceable with respect thereto. Further, the compression means (210) comprises a proximal pressure face (215) for engaging compressively, directly or indirectly, with a distal end of the femur. Thus, when the screw member (20) is positioned in place within the femur, and the compression means (210) are axially advanced proximally along the distal end of the screw member (20), the pressure face (215) and the distal thread surfaces (44) of the screw thread (31) compressively bring together the fractured segments of the femur. Thus, a distal longitudinal force is applied to the screw member (20) by virtue of the reaction of bone tissue on the distal thread surfaces (44) when proximal axial displacement of the compression means (210) urges the screw member (20) in a distal direction.

Referring to Figures 2(a) and 6, the compression means (210) is, in the embodiment of Figure 2(a), in the form of an axially movable first nut element (51) having an internal screw thread (27) complementary to an external screw thread (34) comprised in at least a distal portion of the second cylindrical member (260). Preferably, the proximal end of the first nut element (51) comprises a rounded annular edge (52), and optionally further comprises a pair of diametrically opposed recesses (53) adapted for engagement with a special tool. As will be described hereinbelow, this special tool enables the first nut element (51) to be axially displaced with respect to the screw member (20) by means of a corresponding rotation of the tool.

Antimigration device (300) is accommodated in said cavity (35) and comprises at least one anchoring means having gripping means (320) for anchoring the device (200) in the femur once it has been positioned in place. The anchoring means are selectively extendible in the lateral direction, as will be explained hereinbelow, from a neutral or datum position to an extended position. In the datum position, the gripping means are typically enclosed within an envelope defined by the external surface of the second cylindrical member (260), and in the extended position the gripping means are extended through corresponding said portals, or slots (39) until the gripping means are brought into compressive engagement, substantially laterally, with bony tissue in the femur. In the present invention, the antimigration device (300) represents an improvement over prior art devices, and is characterised in comprising axially movable fixation means (310) which enable a user to selectively set and fix the axial position of the gripping means (320) with respect to the second cylindrical member (260). Thus, once the screw member (20) is positioned and set in place within the femur, the fixation means (310) enables the user to choose precisely where the gripping means (320) should be situated axially with

respect to the screw member (20), enabling the best choice of anchoring site within the femur to be chosen for each individual patient. This versatility in choosing the location of the anchoring site tremendously widens the universal adaptability of the device (200), since the device (200) can be adapted for optimal effect with patients having different optimal anchoring sites.

Thus, referring to Figure 2(a), the antimigration device (300) according to the present invention comprises a proximally disposed ring member (50) substantially coaxial with the axis (230) of the screw member (20). The anchoring means are in the form of a plurality of resilient arms (47) cantilevered from the ring member (50) and extending distally therefrom, one arm (47) corresponding to and aligned with each said slot (39). Each said arm (47) comprises a gripping means (320) at the free distal end thereof, the gripping means (320) being typically in the form of lateral externally facing tabs (22) accommodated within said corresponding slots (39) when the antimigration device (300) is in the datum unextended position. The tabs (22) have a bone-engaging outer edge, which is preferably serrated for improving the traction properties of the gripping means (320) with respect to the bony tissue that it is anchored in.

The axially movable fixation means (310) comprises a cylindrical stub member (62) having an external screw thread complementary to an internal crew thread of said ring member (50). The stub member (62) also comprises a distal end having a substantially diametrical slot (63) for engaging with an external complementary special tool or appropriate screwdriver, for example, and a proximal end (32) for rotatingly abutting against proximal end wall (255) of cavity (35). Thus, with said tabs (22) engaged in their corresponding slots (39), the stub (62) may be rotated via engagement of a tool with slot (63), while the stub (62) is pressed against end wall (255), enabling the ring member (50) to

translate axially, thereby changing the relative axial position between the gripping means (320) and the screw member (20).

The antimigration device (300) further comprises actuation means for reversibly extending the gripping means (320) in a lateral direction. Referring to Figure 2(a), the actuation means comprises an axially movable thrust element (64) accommodated in said cavity (35) and having an external screw thread (321) complementary to and engaged with an internal screw thread (322) comprised in at least a substantial distal portion of the second cylindrical member (260). A proximal end of the thrust element (64) comprises a convex conical surface (65) which is abuts against the inner part of the free end of each arm (47), such that as the thrust element (64) is axially translated in the proximal direction, the diameter of the part of the conical surface (65) in contact with the arms (47) increases, urging the arms (47) laterally outwards. In other embodiments, the thrust element (64) may comprise a proximal arm-engaging leading end having any suitable profile, for example a body of revolution having a parabolic profile, in which at the proximal end of the travel range of the thrust element (64) more revolutions thereof are required than at the distal end to extend the arms (47), providing greater efficiency since the resistance of the bony tissue to the implantation of said tabs (22) generally increases with the depth of implantation. The thrust element (64) comprises a substantially diametrical slot (66) in the distal end thereof for engaging with an external complementary special tool, or a suitable screwdriver for example, so as to enable the thrust member (64) to be axially displaced within the cavity (35) thereby. The length of stub member (62) is such as to provide a substantial spacing between its distal end and the thrust member (64), such as to avoid contact between the stub member (62) and the thrust member (64) for their respective full ranges of axial travel. The said arms (47) while resilient are

biased such that the tabs (22) do not protrude from their corresponding slots (39) at the datum position of the antimigration device (300), i.e., when the thrust member (64) is disengaged from the arms (47).

In a further aspect of universality, and referring to Figures 3, 4 and 6, the device (200) further optionally comprises at least one extension member (24) which is axially engageable with respect to the distal end of said screw member (20). The extension member (24) effectively increases the axial length of the screw member (20), thereby enabling the basic screw member (20) to be used with patients having anatomically larger femurs than for other patients for whom the basic screw member (20) is appropriately sized, such a basic size being typically correlated to an average statistical value for patients. Of course, rather than just one, there may be several extension members (24) of different axial lengths, each of which may be in turn engaged with the screw member (20) to provide the precise total axial length required, and thus quickly and effectively match the needs of each individual patient. Alternatively or additionally, two or more extensions members (24) may be adapted for engaging one with another in series with the screw member (24) to enhance the universality and versatility of the device (200). These aspects of the present invention represent a significant economic advantage in that custom made screw members are not needed for patients having anatomically larger bones. The extension member (24) is typically essentially tubular, and at least a proximal portion thereof comprises an external screw thread (56) which is complementary to and engages with the internal screw thread (322) comprised in the distal portion of the cavity (35). When using an extension member (24), the said compression means (210) are releasably engaged with and selectively axially displaceable with respect to a distal portion of the extension member

(24), rather than with the second cylindrical member (260). Similarly, if more than one extension member (24) is engaged with the second cylindrical member (260) in series, the compression means (210) are typically engaged with the most distal extension member (24).

As illustrated in Figures 3 and 4, the extension member (24) may be a non-stepped tubular extension member (24") having a mean external diameter substantially similar to the mean internal diameter of the distal end of the screw member (20). In other words, the external diameter of the tubuar extension member (24") is complementary to the internal diameter of the second cylindrical member (260), taking into account the corresponding screw threads (56) and (322), respectively. In this case, the compression means (210) comprises an axially movable second nut element (59), having an internal screw thread (256) which is complementary to and engages with the external screw thread (56) comprised in the distal portion of the tubular extension member (24"). Preferably, the proximal end of the second nut element (59) comprises a rounded annular edge. Advantageously, the second nut element (59) also comprises a pair of substantially diametrically opposed recesses (61) on the distal end thereof for engaging with a suitable external complementary tool. The recesses (61) enable the second nut element (61) to axially displaced with respect to the screw member (20) by means of the engagement and rotation of such a tool with the second nut element (59).

As with the second cylindrical member (260), the said tubular extension member (24") may optionally comprise a pair of substantially diametrically opposed radial slots (257) on the distal end thereof for engaging with an external complementary tool. Once the tubular extension member (24") is axially locked with respect to the screw member (20), the slots (257) enable the screw member (20) to be axially advanced into the femur by means of

engagement of this tool with the slots (257), and rotation of the tool, which causes the screw member (20) to rotate as a complete unit with the tubular extension member (24"), and for the screw thread (31) to engage and penetrate into the femur, as will be further described hereinbelow. An advantage of this tubular embodiment (24") of the extension member (24) is that it may be advanced into the said second cylindrical member (260) to any one of a range of depths, and therefore enables the total axial length of the device (200) to be finely tuned and thus matched to a particular patient having anatomical parameters within a predetermined range.

Alternatively, and as illustrated in Figure 6, the extension member (24) may be in the form of a stepped extension member (24') having a proximal portion (258) and a distal portion (54). The proximal portion (258) has an external diameter substantially complementary to the internal diameter of the distal end of the screw member (20), and comprises an external screw thread (56) complementary to and for engaging with internal screw thread (322) of the second cylindrical member (260). The distal portion (54) comprises a larger external diameter, substantially equal to that of the distal end of the screw member (20), and also comprises a similar external screw thread (57) to the external screw thread (34) on the distal end of the second cylindrical member (260). Thus, the compression means (210) that may be used in conjunction with this embodiment (24') of the extension member (24) may be the same nut element (51) that is used with the basic screw member (200), mutatis mutandis. When this embodiment (24') of the extension member (24) is used with the screw member (20), the stepped extension member (24') is screwed into the distal end of the second cylindrical member (260), typically until the proximally facing annular shoulder (259) between distal portion (54) and

proximal portion (258) of the stepped extension member (24') abuts the distal end of the second cylindrical member (260).

The stepped tubular member (24') may also optionally comprise a pair of substantially diametrically opposed radial slots (58) on the distal end thereof for engaging with an external complementary tool. Once this embodiment of the extension member (24') is axially locked with respect to the screw member (20), the slots (58) enable the screw member (20) to be axially advanced into the femur by means of engagement of this tool with the slots (58), and rotation of the tool, which causes the screw member (20) to rotate as a complete unit with the extension member (24'), and for the screw thread (31) to engage and penetrate into the femur, as will be further described hereinbelow. An advantage of this stepped tubular embodiment of the extension member (24') is that it may be used with the same compression means (210) that is used for the basic screw member (20), thereby reducing the number of different components that may be required by a user.

Optionally, said stepped extension member (24') may comprise an internal screw thread at least at the distal end thereof complementary to the external screw thread (56) of another stepped or non-stepped extension member, hereby another extension member to be mounted distally thereto, and thus increase the effective length of the screw member (20).

As illustrated schematically in Figures 2(a), 2(d), 2(e) and 2(f), the device (200) of the present invention may further optionally comprise a locking plate (400) for further securing the screw member (20) to the femur. The locking plate (400) is of particular use when fixating lateral neck fractures, and is mounted to the outer distal surface of the femur, typically close to the under

trochanter area (6) of the bone. While unitary locking plates known in the art may be used in conjunction with said screw member (20), adapted accordingly, the locking plate (400) of the present invention is particularly characterised in comprising an upper plate portion (410) and a lower plate portion (420), and adjustment means (430) for adjusting the relative angular disposition and/or the relative linear displacement between the upper plate portion (410) and the lower plate portion (420). The upper plate portion (410) is adapted for rigid securement to the screw member, typically via the compression means (210), while the lower plate portion (420) is adapted for rigid securement to a distal part of the femur. As illustrated in Figures 2(e) the upper plate portion (410) advantageously comprises a proximal surface having a profile complementary to a upper portion of the distal part of the femur onto which the upper plate portion (410) abuts. Similarly, and as illustrated in Figures 2(f) the lower plate portion (420) advantageously comprises a proximal surface having a profile complementary to a lower portion of the distal part of the femur onto which the lower plate portion (420) abuts. As illustrated in Figure 2(d), the upper plate portion (410) comprises a first aperture (415) adapted for securingly engaging with a distal end of the device (200), and said lower plate portion (420) may be rigidly secured to the distal portion of the femur by at least one, and preferably by as plurality of nails or wood screws, for example, via corresponding apertures (425) comprised in said lower plate portion (420). The relative angular disposition between the upper plate portion (410) and the lower plate portion (420) may be fixed at any desired value, typically according to the geometry of the individual femur and the fractures contained therein by fixing means (500)

Referring to Figures 7 to 12, a first embodiment (67) of the pressure plate (400) comprises an upper plate portion (69) having profiled proximal surface

(73), and a first aperture (70) adapted for engaging with the distal end of device (200). Thus, aperture (70) is of a size to allow the distal end of device (200) to be threaded therethrough, if the device (200) is used without any extension member (24), or alternatively for the distal end of the extension member (24) to protrude therefrom, according to whether the stepped tubular extension member (24') or tubular extension member (24") is used with the device (200). Advantageously, the aperture (70) has a concave rounded edge (71) complementary to the rounded annular edge (52) or (60), according to whether nut element (51) or nut element (59), respectively, is used as the compression means (210). In this embodiment, the pressure plate (400) also comprises a lower plate portion (68) having profiled proximal surface (72) and a plurality of apertures (70) for enabling nails or wood screws to secure the lower plate portion (70) to the femur.

The adjustment means (430) comprises a mechanically detachable hinge arrangement (450) having a first hinge element (451) comprised at the upper end of said lower plate portion (68), and a cooperating second hinge element (452) comprised in said upper plate portion (69) intermediate between the upper end and the lower end thereof. Thus, rotation of the upper plate portion (69) with respect to the lower plate portion (68) via the hinge arrangement (450) enables the relative angular dispositions therebetween to be adjusted.

In the first embodiment (67) of the pressure plate (400), said fixing means (500) comprise at least one screw device (75) having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion (69). The said threaded portion comprises a proximal end engaged with and capable or rotating with respect to said lower plate portion. The said at least one screw device (75) further comprises an actuating portion

(501) for enabling the screw device (75) to be rotated. Thus, actuating portion (501) may be adapted for manually turning the same, or alternately may comprise means such as a diametrical slit or hexagonal pit, for example, for engaging with a suitable external tool so as to enable said screw device (75) to be axially displaced with respect to said upper plate portion (69) by means of corresponding rotation of said external tool.

Referring to Figures 13 to 18, a second embodiment (76) of the pressure plate (400) comprises an upper plate portion (78) having profiled proximal surface (82), and a first aperture (79) adapted for engaging with the distal end of device (200). Thus, aperture (79) is of a size to allow the distal end of device (200) to be threaded therethrough, if the device (200) is used without any extension (24), or alternatively for the distal end of the extension member (24) to protrude therefrom, according to whether the stepped extension member (24') or tubular extension member (24") is used with the device (200). Advantageously, the aperture (79) has a concave rounded edge (80) complementary to the rounded annular edge (52) or (60), according to whether nut element (51) or nut element (59), respectively, is used as the compression means (210). In this embodiment, the pressure plate (400) also comprises a lower plate portion (77) having profiled proximal surface (81) and a plurality of apertures (503) for enabling nails or wood screws to secure the lower plate portion (77) to the femur.

In this embodiment, the adjustment means (430) comprises a mechanically detachable and linearly adjustable hinge arrangement having a first male hinge element (505) comprised at an upper end of said lower plate portion (77) and a cooperating second female hinge element (506) comprised in said upper plate

portion (78), intermediate an upper end and lower end of said upper plate portion (78). The female element (506) comprises a slot (85) for enabling the male element (505) to be engaged therein. The upper end of said upper plate portion (78) comprises said first aperture (79), and said lower end of said upper plate portion (78) comprising said fixing means (500). The said female hinge element comprises a plurality of lateral apertures (86) for selectively articulatingly engaging said male element (505) in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin. Thus, both the relative linear and angular dispositions of the upper plate portion (78) may be adjusted with respect to the lower plate portion (77) by respectively engaging the male element (505) with one of the linear positions corresponding to apertures (86), and by rotating about the hinge formed at that portion with the articulating pin.

In this embodiment, the fixing means (500) comprises a at least one screw device (84) having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion (78). The said threaded portion comprises a proximal end engaged with and capable or rotating with respect to said lower plate portion (77). The said at least one screw device (84) further comprises an actuating portion (508) for enabling the screw device (75) to be rotated. Thus, actuating portion (508) may be adapted for manually turning the same. Preferably, the actuating portion (508) may comprise means such as a diametrical slit, for example, for engaging with a suitable external tool so as to enable said screw device (84) to be axially displaced with respect to said upper plate portion (78) by means of corresponding rotation of said external tool.

Referring to Figures 19 to 24, a third embodiment (87) of the pressure plate (400) comprises an upper plate portion (89) having profiled proximal surface (93), and at least a first aperture (90) adapted for engaging with the distal end of device (200). Thus, aperture (90) is of a size to allow the distal end of device (200) to be threaded therethrough, if the device (200) is used without any extension (24), or alternatively for the distal end of the extension member (24) to protrude therefrom, according to whether the stepped extension member (24') or tubular extension member (24") is used with the device (200). Advantageously, the aperture (90) has a concave rounded edge (91) complementary to the rounded annular edge (52) or (60), according to whether nut element (51) or nut element (59), respectively, is used as the compression means (210). In this embodiment, the pressure plate (400) also comprises a lower plate portion (88) having profiled proximal surface (92) and a plurality of apertures (509) for enabling nails or wood screws to secure the lower plate portion (88) to the femur.

In this embodiment, said adjustment means (430) comprises a linearly adjustable hinge arrangement having a first male hinge element in the form of two parallel distally extending plates (510) comprised at an upper end of said lower plate portion (88), and a cooperating second female hinge element (511) comprised in said upper plate portion (87) intermediate an upper end and lower end of said upper plate portion (87). The female hinge element (511) comprises a plurality of lateral apertures (95) for selectively articulatingly engaging said plates (510) in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion (88) via an articulating pin. Furthermore, the upper end of said upper plate portion (87) comprises at least one and preferably two or more said first aperture (90), and said lower end of

said upper plate portion (87) comprises at least one and preferably tow or more second apertures (90').

The said fixing means (500) is associated with said second aperture (90') comprised in said lower end of said upper plate portion (89). In this embodiment, the fixing means comprises a at least one screw device (not shown) having a first threaded portion engaged with and adapted for axial displacement with respect to complementary threaded aperture comprised in said upper end of said lower plate portion (88). The threaded portion has a distal end that passes through the second aperture (90') comprised in said upper plate portion (89), and the screw device further comprises an actuating portion having means for engaging with a suitable external tool (or manually) so as to enable said at least one screw device to be axially displaced with respect to said lower plate portion (88). The screw device also has a thrust surface for moving the said upper plate portion (89) via the second aperture (90') as the screw device is moved with respect to the lower plate portion (88). In this embodiment, the relative linear disposition between the upper plate portion (89) and the lower plate portion (88) may be adjusted according to via which aperture (95) these portions are hinged, and the corresponding relative angular disposition adjusted by rotation about the hinge. Moreover, further linear adjustment of the whole pressure plate (87) is possible by virtue of the fact that the pressure plate (87) may be mounted to the device (200) via any one of the apertures (90) in the upper part of the upper plate portion (89), which apertures (90) are linearly spaced one from another. Furthermore, the upper plate portion (89) is preferably S-shaped in transverse profile and may be selectively engaged with respect to the said lower plate portion (88) in one of a first or a second orientation corresponding to having said upper end or said lower end respectively, of said upper plate portion (89) uppermost. In such a case, second

apertures (90') are substantially identical to said first apertures (90), and thus in the second orientation any one of apertures (90') is used for securing the pressure plate (87) to the device (200), while the first apertures (90) are associated with the fixing means (500). The upper end and lower ends of the upper plate portion (89) are of different linear lengths to increase the range of linear adjustments possible with this embodiment.

Referring to Figures 25 to 32, a fourth and preferred embodiment (96) of the pressure plate (400) comprises an upper plate portion (98) having profiled proximal surface (101), and a first aperture (99) adapted for engaging with the distal end of device (200). Thus, aperture (99) is of a size to allow the distal end of device (200) to be threaded therethrough, if the device (200) is used without any extension (24), or alternatively for the distal end of the extension member (24) to protrude therefrom, according to whether the stepped tubular extension member (24') or tubular extension member (24") is used with the device (200). Advantageously, the aperture (99) has a concave rounded edge (100) complementary to the rounded annular edge (52) or (60), according to whether nut element (51) or nut element (59), respectively, is used as the compression means (210). In this embodiment, the pressure plate (400) also comprises a lower plate portion (97) having profiled proximal surface (102) and a plurality of apertures (105) for enabling nails or wood screws to secure the lower plate portion (97) to the femur.

In this embodiment, said adjustment means (430) is in the form of a curved lower end (530) comprised in said upper plate portion (98) and having a slot (103). The slot (103) comprises laterally disposed shoulders (525) parallel thereto and cooperating with a male reaction block (520) comprised an upper end of said lower plate portion (97). The said curved lower end (530) and said block (520) comprise suitable profiles such as to enable the area of contact

between said lower end (530) and said block (520) to be adjusted such as to provide at least one of a range of relative angular dispositions and a range of relative linear displacements between said upper plate portion (98) and said lower plate portion (97). Thus, the shoulders (525) may slide along the distal portion (526) of block (520) to adjust the relative linear dispositions of the upper plate portion (98) and the lower plate portion (97). Additionally or alternatively, the shoulders (525) may rotate over the distal portion (526) of block (520) to adjust the relative angular dispositions of the upper plate portion (98) and the lower plate portion (97).

In this embodiment, the fixing means (500) comprises at least one and preferably two screw devices (104) for clamping said upper plate portion (98) to said lower plate portion (97). Each screw device (104) comprises a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded third aperture comprised in the distal portion (526) of said block (520) of said lower plate portion (97). Furthermore, each screw device (104) further comprises a thrust surface for clamping contact with a distal surface of said lower portion (530), and an actuating portion having means for engaging with a suitable external tool so as to enable said at least one screw device to be axially displaced with respect to said lower plate portion, particularly by means of corresponding rotation of said external tool.

Preferably, said slot (103) has an open lower end, enabling the upper plate portion (98) to be attached or detached from the lower plate portion (97) without removing the screw devices (104).

While the pressure plate (400) of the present invention may be advantageously used in conjunction with said screw member (20) (optionally including

extension member (24)) and compression means (210), the said pressure plate (400) is novel per se, and in fact may be used with any suitable femur screw or nail arrangement having a distal end, the upper plate portion (410) being adapted for rigid securement with respect to such a distal end of the femur screw or nail arrangement instead of the screw member (20) / compression means (210) of the present invention, mutatis mutandis.

The device (200) of the present invention is associated with a set of adjusting tools including: a first spiral drill for the bone, a second spiral drill for the bone; a third spiral drill; a screw holder for femur neck osteosynthesis; a special wrench for adjusting the screw for femur neck osteosynthesis together with the antimigration device; a special wrench for adjusting the hold-down and additional nut of the screw for femur neck osteosynthesis; an all-purpose wrench for femur neck osteosynthesis.

Referring to Figure 32, the first spiral drill (106) for the bone has a central axis (107) and a coaxial lumen (108) sized to accommodate an alignment needle, and an outer diameter no less than the inner diameter of thread (31) of screw member (20). The length of the cutting spiral (109) is typically not less than the maximum femur neck length.

Referring to Figure 33, the second spiral drill (110) for the bone also has a central axis (111) and a coaxial lumen for accommodating the alignment needle. The outer diameter of the second drill is greater than the inner diameter of thread (31) and serves to drill tolerance in bone material. The length of cutting spiral (113) is typically not less than the maximum femur neck length.

Referring to Figure 34, the third spiral drill (114) for the bone has an outer

diameter greater than the outer diameter of the second cylindrical member (260), and the length of the cutting spiral is typically not less than the length of the second cylindrical member (260).

Referring to Figures 35 and 36, screw holder (116) for femur neck osteosynthesis comprises a body (117) having a handle (118) at a distal end thereof, and an axial well (119) on the proximal end thereof. The well (119) comprises an internal screw thread (550) complementary to the external screw thread (34) of screw member (20). Holder (116) further comprises a lumen (120) coaxial with a central axis thereof and extending through said body (117) and handle (118), the lumen (120) being sized to accommodate said alignment needle. Holder (116) is used for imparting rotary movement to screw member (20) and thus enabling the screw member (20) to be driven into the proximal part of femur neck. Screw member (20) is implanted into the proximal part of femur neck without extension sleeve, when this is also needed, the extension sleeve being subsequently engaged with screw member (20) separately, after removing holder (116).

Referring to Figures 37 to 39, a special wrench (121) may be used for adjusting the screw member (20) for femur neck osteosynthesis together with antimigration device (300). Such a wrench is disclosed in SU 1715335, the contents of which are included herein in their entirety by reference thereto. Wrench (121) comprises a body portion (122) having a handle (123) at a distal end thereof, and further comprising a well (124) on the proximal end of the body portion (122). At least a proximal portion of the external surface (125) of body portion (122) comprises an external screw thread (126), and two diametrically opposed longitudinal slots (127) are formed in the body within the externally threaded portion of the body portion (122). A reciprocable spring-loaded actuator in the form of a tab (128) has its lateral ends extending

through said longitudinal slots, enabling the tab to slide axially between the ends of the slots (127). The lateral ends of the tab (128) are enclosed within a hollow nut member (129) having an internal screw thread complementary to and engaged with said external screw thread (126), enabling the nut member (129) to be axially translated over the body member (122), taking said tab (128) therewith. Tab (128) is biased in the proximal direction by means of a pushing element (130) coupled to a spring (131) comprised in the body portion (122). This wrench (121) is typically applied when the bone material offers a considerable resistance to the implantation of screw member (20), wherein considerable effort is required to drive it in and then to separate wrench (121) from screw member (20). Furthermore, wrench (121) is also particularly useful for removing screw member (20) from the femur once the osteosynthesis process has been completed and complete union of femur neck chips has occurred (according to medical indications or the patient's desire).

Referring to Figures 40 and 41, a special wrench (132) is provided for adjusting nut members (51) or (59). The wrench (132) comprises a body (133) having a turning handle (134) disposed at a distal end thereof. The proximal end of the body (133) comprises a well (135) adapted for receiving a distal end of second cylindrical member (260) (or the distal end of extension member (24), and has an internal diameter greater that the external diameter thereof including a radial clearance therebetween. A pair of diametrically opposed pins (136) are arranged on the annular distal face (555) of the body (133). The pins (136) are adapted for registration and engagement with recesses (53) or (61) comprised in nut members (51) and (59), respectively.

Referring to Figures 42 and 43, the set of adjusting tools further includes all-purpose wrench (137) comprising an elongate body (138) having a detachable handle intermediate the axial ends thereof. On one end of body

(138) are comprised means for imparting rotary motion to screw member (20) or to extension sleeve (54), and such means include a step-shaped ribbed pin (140) having diametrically opposed axial ribs (141) which are adapted for registration and engagement with slits (21) or (58), respectively. On the other axial end of body (138) a well (142) is provided with a pair of diametrically opposed axially projecting flanges (143). Said flanges are adapted for registering and engaging with complementary recesses (145) comprised at one end of an elongate element (144). The other end of elongate element (144) comprises a tab (146) adapted to engage lateral slot (63) or (66) of said stub (62) or thrust member (64), respectively. All-purpose wrench (137) is typically used after screw member (20) has been fully driven into the bone, and it is necessary to deepen it proximally a little further to mount the extension sleeve. Furthermore, the wrench (137) is also particularly useful for mounting the extension sleeve, as well as (in combination with additional element (144) for adjusting the location of the antimigration device (300) with respect to stub (62), or for actuating the antimagration device (300) by means of thrust member (64).

The device (200) of the present invention may be used as follows..

Fracture fragments are reponed under periodic X-ray observation. A 3-4 cm long cut is made to expose undertrochanter area (6) of the femur. In the spot wherein Trochanter major changes to Diafiz (8) an alignment needle is passed, by means of a drill, in direction of the femur neck axis (19). The bone cortical layer (7), approximately 2 cm thick, around the distal end of the needle, is removed typically with a chisel. Then, under periodic X-ray monitoring, a stepped bore is drilled out in the femur using in succession first spiral drill

(106), second spiral drill (110) and third spiral drill (114), as illustrated in Figure 44. The first spiral drill (106) and second spiral drill (110) are aligned by means of lumens (108), (112) respectively and the alignment needle, and each drill is in turn advanced proximally along the femur neck axis (19) using the alignment needle as a guide rod. The drilling depth for each of the first drill (106) and for the second drill (110) is a little greater than the length of screw member (20). Particularly in the case of elderly patients, sometimes only the first drill (106) is needed, since introduction of the screw member (20) does not pose too great a resistance given the close tolerance between the first cylindrical member (220) and the bore created by the first drill (106). However, with younger patients, the resistance is generally greater and therefore greater dimensional tolerance is required, and this is accomplished by drilling a wider bore with second drill (110), in addition to or instead of the original bore drilled out by the first drill (106). The third spiral drill (114) is typically advanced by a brace to the depth of this part of the bore which exceeds a little the length of second cylindrical member (260), thereby expanding radially the distal part of the bore drilled by the first drill (106) and second drill (110). In cases where the third drill also comprises an axial lumen, the alignment needle may be used instead of the brace for aligning the third drill.

Referring to Figure 45, the screw member (20) is driven into the femur along axis (19) by rotating same about its axis (230) using holder (116), wherein the distal end of screw member (20) is engaged in well (119) thereof, and relative axial movement between member (20) and the holder (116) is prevented by nut member (51). The screw member (20) is advanced proximally into the full length of the wider part of the bore drilled by the third drill (114), and then driven into the remaining proximal part of this bore using the elf-taping screw

thread (31).

Bone chips generated in the self-tapping process fill grooves (42) comprised in the mid-section of the first cylindrical body. Referring to Figure 4, the lumen (29) may used in conjunction with the alignment needle as a guide rod to align the screw member (20) more precisely. To this end the alignment needle is passed in through lumen (29) and cavity (35) of the screw member (20) (the antimigration device (300) having been removed previously), and in through the lumen (120) of holder (116). Once screw member (20) has been driven into the femur, the holder (116) is separated from screw member (116), for example by first advancing the nut member (51) in a proximal direction and then rotating the holder (116) so that it translates in a distal direction. Then, the antimigration device (300) is mounted into the cavity (35) via the distal end of the screw member (20). Such a procedure of setting screw member (20) is used when the severity of bone osteoporosis is very high.

Preferably, and referring to Figure 46, the screw member (20) is implanted together with the antimigration device (300). Advantageously, special wrench (121) may be used for this purpose, wherein screw member (20) is initially engaged by its external screw thread (34) with the threaded well (124) up to abutment with nut member (51). Then, tab (128) is advanced proximally via hollow nut (129) until it engages with slits (21), and then the screw member (20) is driven proximally by turning handle (123) of the special wrench (121) This is carried out in a similar manner as with holder (116). Once screw member (20) has been implanted to the required depth, the special wrench (121) is separated therefrom. To facilitate this uncoupling hollow nut (129) is rotated to advance slightly in a proximal direction, wherein tab (128) is slightly

advanced along slits (127) and acting axially on slits (21).

Once screw member (20) has been fully implanted, femur head (2) and neck (3) are brought together and held down in compression. To this end special wrench (132) is used to turn nut member (51) via pins (136) and recesses (53), until nut member (51) is pressed against the bone cortical surface (7). Tightening the nut member (51) further provides a distal force to the screw thread (31) and a reaction force to the pressure face (215), causing compression of the bone endosteum. The femur head (2) and neck (3) are thus made coincident and pressed together tightly.

If the length of screw member (20) is inadequate, it can be increased by using one or several extension sleeves (24), for example. The extension member (24) is partly screwed in along thread (36) into internal axial cavity (35) by means of all-purpose wrench (137). If the tubular extension member (24") is used, then to hold together femur head (2) and neck (3), second nut element (59) may be used, and this may also be screwed in place using special wrench (137). Of course, if the stepped extension member (24') is used, then the first nut element (51) can be used as with the basic screw member (20).

Referring to Figure 47, when the bone parts are brought together in compression, antimigration device (300) is positioned in the desired place and fixed. To position antimigration device (300) in the desired place threaded stub (62) is turned by means of additional element (144) of all-purpose wrench (137), for example, causing ring member (50) to advance axially within cavity (35) (under periodic X-ray monitoring) until the ends of its arms (47) come into the necessary position inside the bone, near cortical layer (7). Then the arms (47) drawn aside and extended from slots (39) by means of thrust member (64)

as this is advanced proximally by means of the additional element (144), for example. The tabs (48) are then driven into the bone and the antimigration device (300) is fixed in the desired position and a paddle-like anchoring system is formed to hold screw member (20) inside the bone and minimise mobility and rotation of bone fragments.

Particularly for use in treating lateral undertrochanter, intertrochanter and transtrochanter fractures of femur neck, pressure plate (400) may be mounted onto the femur external surface near undertrochanter area (6), using the following generalised procedure. Screw member (20) is mounted to the femur as described above, and bone parts are brought into coincidence compressively by tightening nut member (51) (or nut member (59) if the tubular extension member (24") is also used), antimigration device (300) is set in necessary position and fixed. Next, the nut member (51) is unscrewed, pressure plate (400) is mounted onto screw member (20), and then nut member (51) re-screwed onto screw member (20) to rigidly hold in place pressure plate (400) with respect to the screw member (20). A similar procedure is used with nut member (59), mutatis mutandis. In these cases, the pressure plate (400) also acts as a washer between the nut member and the bone. If the pressure plate is a unitary plate, it is then fixed to the femur in the usual manner. When using the pressure plate according to the present invention, fixing of the pressure plate (400) to the femur is effected when the desired angular and/or linear dispositions between the upper plate portion (410) and the lower plate portion (420) is adjusted and fixed, as will be described below in the context of several embodiments of said pressure plate (400).

Referring to the first embodiment of the pressure plate (67) illustrated in

Figures 7 to 12, and to Figure 48, the upper plate portion (69) is rigidly attached to the distal end of screw member (20) via aperture (70) and by screwing nut member (51) or nut member (59) to screw member (20). Then, the lower plate portion (68) is mounted to the upper plate portion (69) via the hinge arrangement (450). To suit patients with different anthropometric dimensions of femur neck, both parts of pressure plate (67), the upper plate portion (69) and the lower plate portion (68) are matched within a certain range of angular and/or spatial positions by detachable articulated hinge arrangement (450), and this is performed until pressure plate (67) tightly fits to femur undertrochanter area (6). Then, the upper plate portion (69) and the lower plate portion (68) are rigidly fixed together in this position by screw device (75). Then lower plate portion (68) is rigidly mounted, by means of nails and/or wood screws to the external surface of femur undertrochanter area (6) via apertures (74), which are preferably in staggered arrangement as illustrated in Figure 10 to provide more reliable attachment of pressure plate (67) to femur undertrochanter area (6). Proximal surfaces, (72) and (73) of the pressure plate (67) have profiles complementary in relation to the adjacent external surface of femur undertrochanter area (6) to provide better fit therebetween.

Referring to Figures 13 to 18 and 49, the second embodiment of the pressure plate (76) is mounted in a similar manner as for the said first embodiment (67), mutatis mutandis.

Thus, the upper plate portion (78) is rigidly attached to the distal end of screw member (20) via aperture (79) and by screwing nut member (51) or nut member (59) to screw member (20). Then, the lower plate portion (77) is mounted to the upper plate portion (78) via the hinge arrangement, i.e., the male hinge element (505) an the female hinge element (506). To suit patients with different anthropometric dimensions of femur neck, both parts of pressure

plate (67), the upper plate portion (69) and the lower plate portion (68) are matched within a certain range of angular and/or spatial positions by means of the apertures (86) and corresponding articulating pin, and this is performed until pressure plate (76) tightly fits to femur undertrochanter area (6). Then, the upper plate portion (78) and the lower plate portion (77) are rigidly fixed together in this position by screw device (84). Then lower plate portion (77) is rigidly mounted, by means of nails and/or wood screws to the external surface of femur undertrochanter area (6) via apertures (503), which are preferably in staggered arrangement as illustrated in Figure 16 to provide more reliable attachment of pressure plate (76) to femur undertrochanter area (6). Proximal surfaces, (81) and (82) of the pressure plate (76) have profiles complementary in relation to the adjacent external surface of femur undertrochanter area (6) to provide better fit therebetween.

Referring to Figures 19 to 25 and 50, the third embodiment of the pressure plate (87) is mounted in a similar manner as for the said first embodiment (67) and said second embodiment (76), mutatis mutandis.

Thus, the upper plate portion (87) is rigidly attached to the distal end of screw member (20) via one aperture (90) and by screwing nut member (51) or nut member (59) to screw member (20). Then, the lower plate portion (88) is mounted to the upper plate portion (89) via the hinge arrangement, i.e., the male hinge element (510) and the female hinge element (511). To suit patients with different anthropometric dimensions of femur neck, both parts of pressure plate (87), the upper plate portion (89) and the lower plate portion (88) are matched within a certain range of angular and/or spatial positions by means of the apertures (95) and corresponding articulating pin, and this is performed

until pressure plate (87) tightly fits to femur undertrochanter area (6). Then, the upper plate portion (89) and the lower plate portion (88) are rigidly fixed together in this position by screw device via aperture (90'). Then lower plate portion (88) is rigidly mounted, by means of nails and/or wood screws to the external surface of femur undertrochanter area (6) via apertures (509), which are preferably in staggered arrangement as illustrated in Figure 19 to provide more reliable attachment of pressure plate (87) to femur undertrochanter area (6). Proximal surfaces, (92) and (93) of the pressure plate (87) have profiles complementary in relation to the adjacent external surface of femur undertrochanter area (6) to provide better fit therebetween.

In this embodiment, the upper plate portion (89) is designed to be mountable onto the lower plate portion (88) in any one of two opposed orientations, in order to increase the versatility of the pressure plate (87). Thus, under certain conditions, particularly relating to the specific anthropometric dimensions of particular patients, the said upper plate portion (89) may be turned around by 180°, and connected to the screw member (20) via aperture (90') instead of aperture (90), to achieve tighter fit to femur undertrochanter area (6).

Referring to Figures 25 to 31 and 51, the fourth embodiment of the pressure plate (96) is mounted in a similar manner as for the said first embodiment (67), second embodiment (76) and third embodiment (87), mutatis mutandis.

Thus, the upper plate portion (98) is rigidly attached to the distal end of screw member (20) via aperture (99) and by screwing nut member (51) or nut member (59) to screw member (20). Then, the lower plate portion (97) is mounted to the upper plate portion (98) via the curved lower end (530) and block (520). To suit patients with different anthropometric dimensions of femur

neck, both parts of pressure plate (96), the upper plate portion (98) and the lower plate portion (97) are matched within a certain range of angular and/or spatial positions by means of rotating and/or translating the shoulders (525) with respect to the distal portion (526) of block (520). Preferably at least one screw device (104) is partially engaged in said block (520) to facilitate this procedure, which is performed until pressure plate (96) tightly fits to femur undertrochanter area (6). Then, the upper plate portion (98) and the lower plate portion (97) are rigidly fixed together in this position by a pair of screw devices (104). Then lower plate portion (97) is rigidly mounted, by means of nails and/or wood screws to the external surface of femur undertrochanter area (6) via apertures (105), which are preferably in staggered arrangement as illustrated in Figure 29 to provide more reliable attachment of pressure plate (96) to femur undertrochanter area (6). Proximal surfaces, (101) and (102) of the pressure plate (96) have profiles complementary in relation to the adjacent external surface of femur undertrochanter area (6) to provide better fit therebetween.

Similarly, said pressure plate (400), in particular the first, second, third and fourth embodiments thereof, (67), (76), (87) and (96) respectively, may be adapted for mounting to a femur in conjunction with a regular femur screw or nail instead of said device (200) using a similar procedure as described above with reference to Figures 48 to 51, mutatis mutandis.

Where necessary, screw member (20) may be removed after the union of femur neck parts. For this purpose the above procedure is carried out in the reverse order. First thrust member (64) is removed, then, by turning axial threaded stub

(62), the arms (46) of antimigration device (300) are moved inside axial cavity (35), opening thereby its release tabs (48) and retracting them into slits (39). Thereafter, by means of special wrench nut member (51) is unscrewed and pressure plate (400) is removed (if it has been mounted). This is performed in an order reverse to that of setting the screw member (20). Thereupon screw member (20) is removed from the femur neck. To facilitate the removal of screw member (20), the proximal end of screw thread (31) is formed as a screw tap, which is thus used for cutting off excrescences of bone tissue which have grown in the bore in the femur neck wherefrom screw member (20) is removed. The removal of screw member (20) is typically performed under periodic X-ray monitoring.

Each component of the device (200), including screw member (20), nut member (51) (or nut member (59), as necessary), antimigration device (300), extension member (24) and pressure plate (400), is made from a medically compatible material, typically titanium, for example.

Application of the claimed device for femur neck osteosynthesis provides accurate and secure matching of bone fragments in compression during the whole period of the fracture union. Further, the duration of surgical interference is essentially reduced and traumatization of endosteum and bone marrow of the femur head and neck is insignificant. The claimed device is suitable for compression treatment of all kinds of femur neck fractures, including medial fractures, such as subcapital fracture and lateral fractures, including undertrochanter fractures. And finally the claimed device is adapted to any anthropological parameters of different patients, easily mounted and, when necessary, easily removed.

Thus, screw member (20) in combination with nut member (51) (or nut member (59), as necessary), antimigration device (300), optionally extension member (24) and pressure plate (400) form a unifiable integrated spatial system which provides reliable compression fixing of bone fragments for patients having different anthropometric dimensions and for any kind of femur neck fractures, including undertrochanter, intertrochanter and transtrochanter lateral fractures. Thus, the present invention provides a universal means for reliable osteosynthesis of all known femur neck fractures.

While in the foregoing description describes in detail only a few specific embodiments of the invention, it will be understood by those skilled in the art that the invention is not limited thereto and that other variations in form and details may be possible without departing from the scope and spirit of the invention herein disclosed.

Claims: -

1. A device for fixating a fractured femur, comprising :-

(a) an elongated screw member adapted for penetrating into at least the neck portion of a femur, comprising :-

a proximal portion comprising a first cylindrical member having an external first screw thread adapted for distal compressive engagement with bony tissue in particular within the femur;

a distal portion comprising a second cylindrical member having an internal cavity and a substantially open distal end, and at least one lateral portal for enabling communication between said cavity and an outside of said second cylindrical member;

an antimigration device accommodated in said cavity and comprising at least one anchoring means having gripping means, said at least one anchoring means being selectively extendable such that said gripping means extends to said outside of said distal portion via a corresponding one of said at least one portal, said gripping means being adapted for anchoring said antimigration device within bony tissue when said gripping means is brought into engagement therewith;

and

(b) compression means releasably engageable with said distal portion of said screw member and selectively axially displaceable with respect thereto, said compression means having a proximal pressure face;

characterised in that said antimigration device comprises axially movable fixation means for selectively setting and fixing the relative axial position of said gripping means with respect to said second cylindrical member.

2. A device for fixating a fractured femur as claimed in claim 1, wherein said first cylindrical member is integrally joined to said second cylindrical member.

3. A device for fixating a fractured femur as claimed in claim 1, wherein said first screw thread comprises an external diameter substantially similar to an external diameter of said second cylindrical member.

4. A device for fixating a fractured femur as claimed in claim 1, wherein said first cylindrical member comprises and axial lumen extending therethrough and having a proximal opening in said first cylindrical member and in communication with said cavity, said axial lumen and said cavity being of a size sufficient to enable a suitable alignment needle to be accommodated therein.

5. A device for fixating a fractured femur as claimed in claim 3, wherein at least the proximal end of said first screw thread is self-taping with respect to bony tissue.

6. A device as claimed in claim 5, wherein said at least proximal end of said screw thread comprises a plurality of circumferentially spaced radial slots to provide portions of said screw thread in the form of blade-like elements separated by said radial slots, said blade like elements having leading edges adapted for taping into bony tissue.

7. A device as claimed in claim 3, wherein said first screw thread comprises at least distal thread surfaces adapted for compressive engagement with bony tissue in response to a distal longitudinal force applied to said screw member.

8. A device as claimed in claim 7, wherein said distal thread surfaces of said first screw thread comprises a distal tilt angle of between about 2° to about 4°.

9. A device for fixating a fractured femur as claimed in claim 3, wherein said first screw thread comprises proximal thread surfaces having a proximal tilt angle of between about 30° to about 35°.

10. A device for fixating a fractured femur as claimed in claim 1, wherein said proximal portion of said screw member comprises at least one longitudinal groove for facilitating transportation of bony tissue debris from the proximal end to the distal end of said first cylindrical member during implantation of said device.

11. A device for fixating a fractured femur as claimed in claim 1, wherein said at least one portal is in the form of a longitudinal slit along the cylindrical wall of said second cylindrical member.

12. A device for fixating a fractured femur as claimed in claim 1, wherein said antimigration device comprises a proximally disposed ring, substantially coaxial with said second cylindrical member, and wherein said at least one anchoring means is in the form of a corresponding resilient arm cantilevered from said ring and extending substantially distally therefrom, said arm having a corresponding said at least one gripping means at the free distal end thereof, said antimigration device further comprising actuation means for reversibly extending said gripping means in a lateral direction .

13. A device for fixating a fractured femur as claimed in claim 12, wherein said actuation means comprises an axially movable thrust element having an external second screw thread complementary to and engaged with an

internal third screw thread comprised at least in a distal portion of said cavity of said second cylindrical member, wherein a proximal end of said thrust element comprises a convex conical surface, said conical surface adapted to abut against and urge said free end of said at least one arm laterally outwards in response to an axial translation in the proximal direction by said thrust element.

14. A device for fixating a fractured femur as claimed in claim 13, wherein said thrust element comprises a substantially diametrical slot on the distal end thereof for engaging with an external complementary first tool so as to enable said thrust member to be axially displaced within said cavity by means of corresponding rotation of said first tool.

15. A device for fixating a fractured femur as claimed in claim 12, wherein said gripping means comprises an externally facing tab having at least one bone-engaging edge.

16. A device for fixating a fractured femur as claimed in claim 15, wherein said bone-engaging edge is serrated.

17. A device for fixating a fractured femur as claimed in claim 15, wherein said at least one arm is biased such that said tab does not significantly protrude from said corresponding at least one portal when said actuation means is disengaged from said anchoring means.

18. A device for fixating a femur as claimed in claim 12, wherein said axially movable fixation means for selectively setting and fixing the relative axial position of said gripping means with respect to said second cylindrical member comprises a stub member engaged with and axially movable with respect to said ring member, said stub member having a proximal end for

rotatably abutting against a proximal end of said cavity, and a distal end axially spaced from said engagement means.

19. A device for fixating a femur as claimed in claim 18, wherein said stub member comprises an external fourth screw thread complementary to and engaged with an internal fifth screw thread comprised in said second ring member.

20. A device for fixating a femur as claimed in claim 19, wherein said distal end of said stub member comprises a substantially diametrical slot for engaging with an external complementary second tool so as to enable said ring member to be axially displaced respect to said stub member by means of corresponding rotation of said second tool.

21. A device for fixating a fractured femur as claimed in claim 1, wherein said compression means comprises an axially movable first nut element having an internal sixth screw thread complementary to and engaged with an external seventh screw thread comprised at least in a distal portion of said second cylindrical member.

22. A device for fixating a fractured femur as claimed in claim 21, wherein a proximal end of said first nut element comprises a rounded annular edge.

23. A device for fixating a fractured femur as claimed in claim 21, wherein said first nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said screw member by means of corresponding rotation of said third tool.

24. A device for fixating a fractured femur as claimed in claim 1, wherein said second cylindrical member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said screw member to be axially advanced into a femur by means of corresponding rotation of said fourth tool.

25. A device for fixating a fractured femur as claimed in claim 1, further comprising an axially engageable longitudinal extension member for effectively increasing the axial length of said screw member, wherein at least a proximal portion of said extension member comprises an external second screw thread complementary to and engaged with an internal third screw thread comprised at least in a distal portion of said cavity of said second cylindrical member, and wherein said compression means is releasably engageable with a distal portion of said extension member and selectively axially displaceable with respect thereto.

26. A device for fixating a fractured femur as claimed in claim 25, wherein said extension member is a tubular member having an external diameter substantially complementary to the internal diameter of said distal end of said screw member.

27. A device for fixating a fractured femur as claimed in claim 26, wherein said compression means comprises an axially movable second nut element having an internal eighth screw thread complementary to and engaged with said external second screw thread comprised in a distal portion of said extension member.

28. A device for fixating a fractured femur as claimed in claim 27, wherein a proximal end of said second nut element comprises a rounded annular edge.

29. A device for fixating a fractured femur as claimed in claim 27, wherein said second nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary fifth tool so as to enable said second nut element to be axially displaced within with respect to said extension member by means of corresponding rotation of said fifth tool.

30. A device for fixating a fractured femur as claimed in claim 26, wherein said extension member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary sixth tool so as to enable said extension member to be axially displaced with respect to said screw member by means of corresponding rotation of said sixth tool.

31. A device for fixating a fractured femur as claimed in claim 25, wherein said extension member is a stepped tubular member having a proximal portion and a distal portion, wherein said proximal portion of said tubular member comprises an external diameter substantially complementary to the internal diameter of said distal end of said screw member, and wherein said distal portion of said tubular member comprises an external diameter substantially equal to the external diameter of said distal end of said screw member.

32. A device for fixating a fractured femur as claimed in claim 31, wherein said compression means comprises an axially movable first nut element having an internal sixth screw thread complementary to and engaged with an external seventh screw thread comprised in at least a distal portion of said extension member.

33. A device for fixating a fractured femur as claimed in claim 32, wherein a proximal end of said second nut element comprises a rounded annular edge.

34. A device for fixating a fractured femur as claimed in claim 32, wherein said first nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said extension member by means of corresponding rotation of said third tool.

35. A device for fixating a fractured femur as claimed in claim 32, wherein said extension member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said extension member to be axially displaced with respect to said screw member by means of corresponding rotation of said fourth tool.

36. A device for fixating a fractured femur as claimed in any one of claims 1 to 35, wherein further comprising a locking plate for further securing said screw member to a femur, said locking plate characterised in having an upper plate portion, a lower plate portion and adjusting means for adjusting at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion, and wherein said upper plate portion is adapted for rigid securement to said screw member via said compression means, and wherein said lower plate portion is adapted for rigid securement with respect to a distal portion of the femur.

37. A device for fixating a fractured femur as claimed in claim 36, wherein said lower plate portion comprises a proximal surface having a profile complementary to a lower portion of said distal portion of the femur.

38. A device for fixating a fractured femur as claimed in claim 37, wherein said lower plate portion may be rigidly secured to said distal portion of said femur by at least one suitable screw via a corresponding at least one aperture comprised in said lower plate portion.

39. A device for fixating a fractured femur as claimed in claim 36, wherein said upper plate portion comprises a proximal surface having a profile complementary to an upper portion of said distal portion of the femur.

40. A device for fixating a fractured femur as claimed in claim 36, wherein said upper plate portion comprises a first aperture adapted for securingly engaging with a distal end of said device, and wherein said compression means compressively engages proximally with a distal end of said femur via said upper plate portion.

41. A device for fixating a fractured femur as claimed in claim 40, further comprising fixing means for fixing at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion.

42. A device for fixating a fractured femur as claimed in claim 40, wherein said compression means is in the form of a nut member having a rounded proximal annular edge, said first aperture having a flared distal entry complementary shaped to said rounded proximal annular edge.

43. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means comprises a hinge arrangement having a first hinge

element comprised at an upper end of said lower plate portion and a cooperating second hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, said upper end of said upper plate portion comprising said first aperture and said lower end of said upper plate portion comprising said fixing means.

44. A device for fixating a fractured femur as claimed in claim 43, wherein said fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion, said threaded portion having a proximal end rotatably engaged with said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

45. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means comprises a linearly adjustable hinge arrangement having a first male hinge element comprised at an upper end of said lower plate portion and a cooperating second female hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, said upper end of said upper plate portion comprising said first aperture and said lower end of said upper plate portion comprising said fixing means, wherein said female hinge element comprises a plurality of lateral apertures for selectively articulatingly engaging said male element in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin.

46. A device for fixating a fractured femur as claimed in claim 45, wherein said fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion, said threaded portion having a proximal end for abutting against a distal surface of said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

47. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means comprises a linearly adjustable hinge arrangement having a first male hinge element comprised at an upper end of said lower plate portion and a cooperating second female hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, wherein said female hinge element comprises a plurality of lateral apertures for selectively articulatingly engaging said male element in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin, wherein said upper end of said upper plate portion comprises at least one said first aperture, and wherein said lower end of said upper plate portion comprises at least one said second aperture, said fixing means being associated with any one of said at least one second aperture.

48. A device for fixating a fractured femur as claimed in claim 47, wherein said upper plate portion may be selectively engaged with respect to the said lower plate portion in one of a first or a second orientation corresponding to having said upper end or said lower end respectively, of said upper plate portion uppermost, wherein said at least one second apertures are

substantially identical to said at least one first apertures, and wherein in said second orientation, one said second aperture is associated with said device and one said first aperture is associated with said fixing means.

49. A device for fixating a fractured femur as claimed in claim 48, wherein said fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to complementary threaded said second aperture comprised in said lower end or in said upper end of said upper plate portion, when said upper plate element is in said first or said second orientation, respectively, said threaded portion having a proximal end for abutting against a distal surface of said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

50. A device for fixating a fractured femur as claimed in claim 48, wherein said upper plate portion has a substantially S-shaped transverse cross-section.

51. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means is in the form of a curved lower end comprised in said upper plate portion, said slot having laterally disposed shoulders parallel thereto and cooperating with a male reaction block comprised an upper end of said lower plate portion, wherein said curved lower end and said block comprising suitable profiles such as to enable the area of contact between said lower end and said block to be adjusted such as to provide at least one of a range of relative angular dispositions and a range of relative

linear displacements between said upper plate portion and said lower plate portion.

52. A device for fixating a fractured femur as claimed in claim 51, wherein said fixing means comprises at least one screw device for clamping said upper plate portion to said lower plate portion, said at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded third aperture comprised in said block of said lower plate portion, and wherein said at least one screw device further comprises a thrust surface for clamping contact with a distal surface of said lower portion, and an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said lower plate portion by suitable means.

53. A device for fixating a fractured femur as claimed in claim 52, wherein said fixing means comprises two said screw devices disposed along the length of said block.

54. A device for fixating a fractured femur as claimed in claim 51, wherein said slot has an open lower end.

55. A device for fixating a fractured femur as claimed in any one of claims 1 to 35, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur.

56. A device for fixating a fractured femur as claimed in claim 36, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur via said upper plate portion.

57. A device for fixating a fractured femur as claimed in any one of claims 37 to 54, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur via said upper plate portion.

58. A device for fixating a fractured femur, substantially as herein described with reference to the accompanying figures.

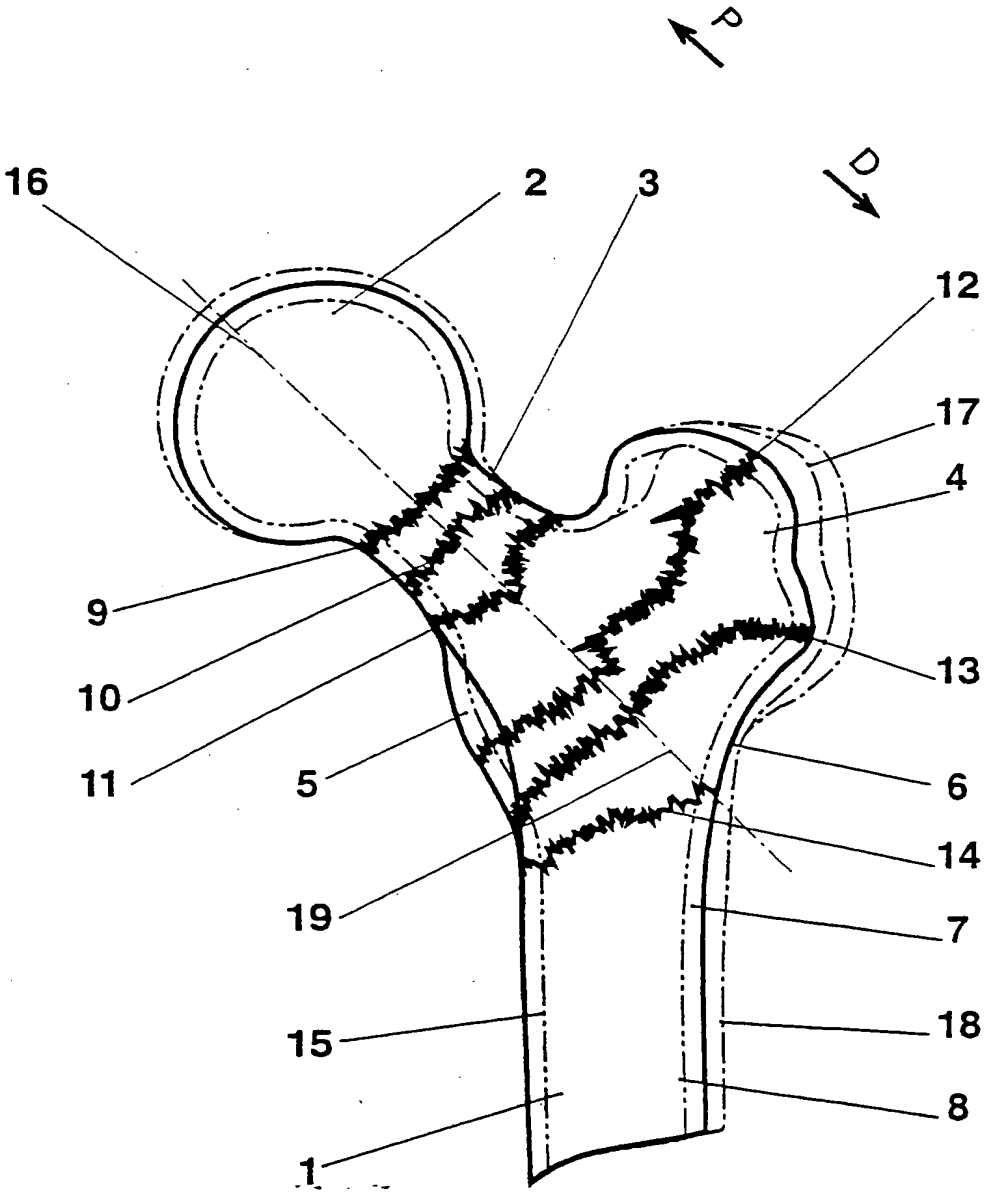

FIG.1

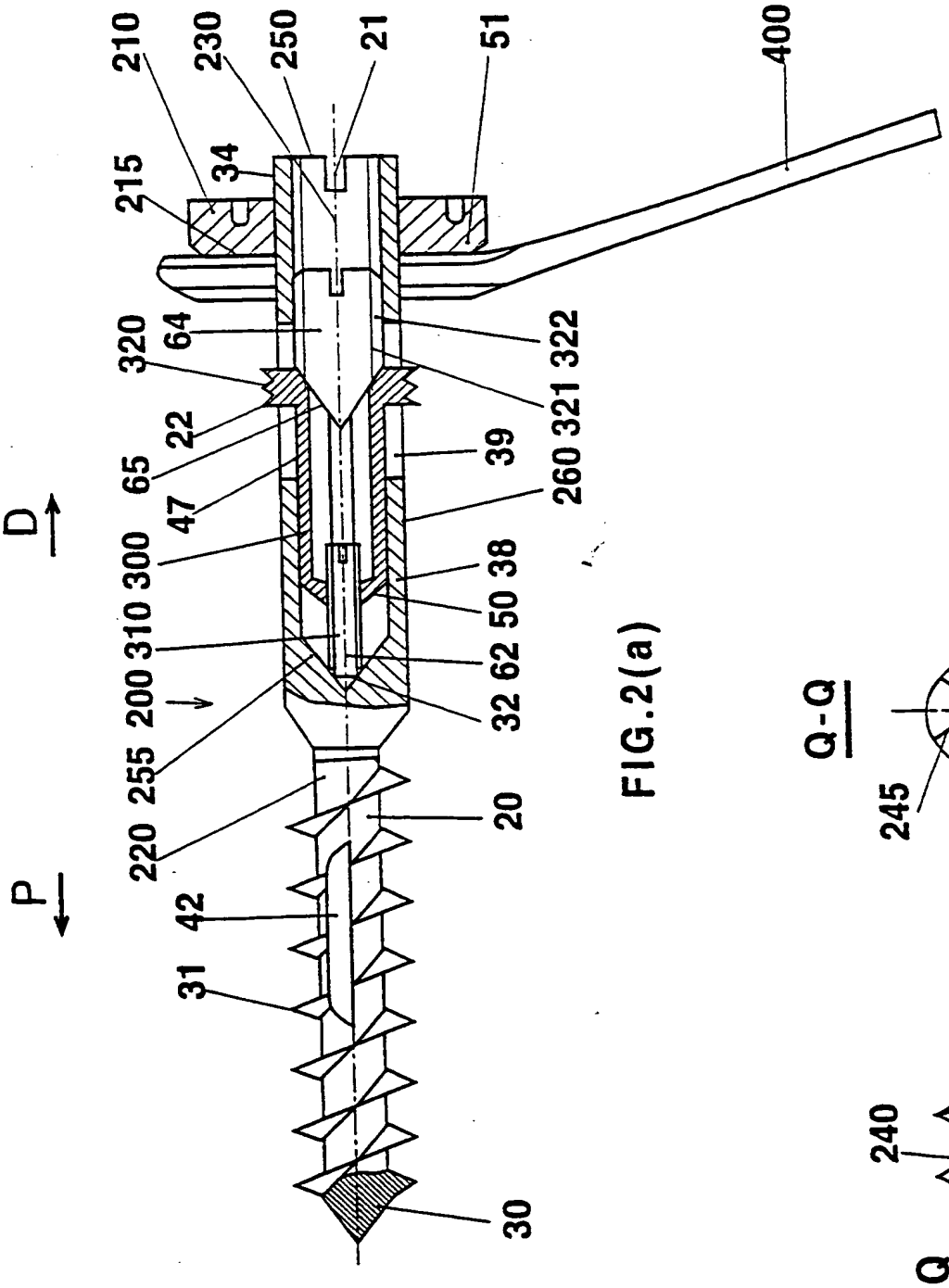

FIG.2(a)

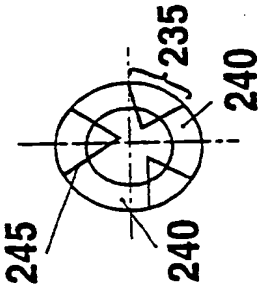

FIG.2(c)

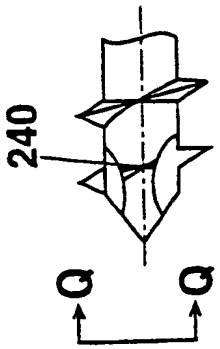

FIG.2(b)

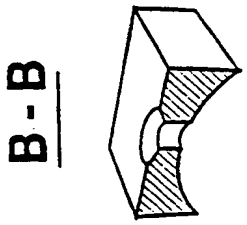

FIG.2(f)

FIG.2(e)

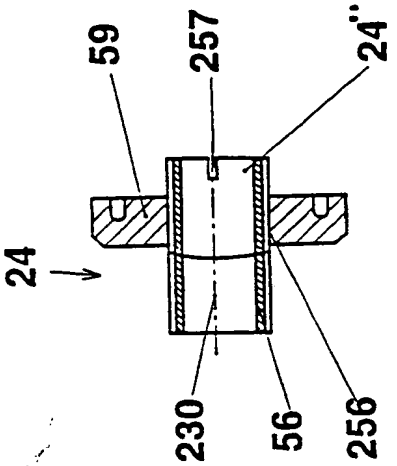

FIG.3

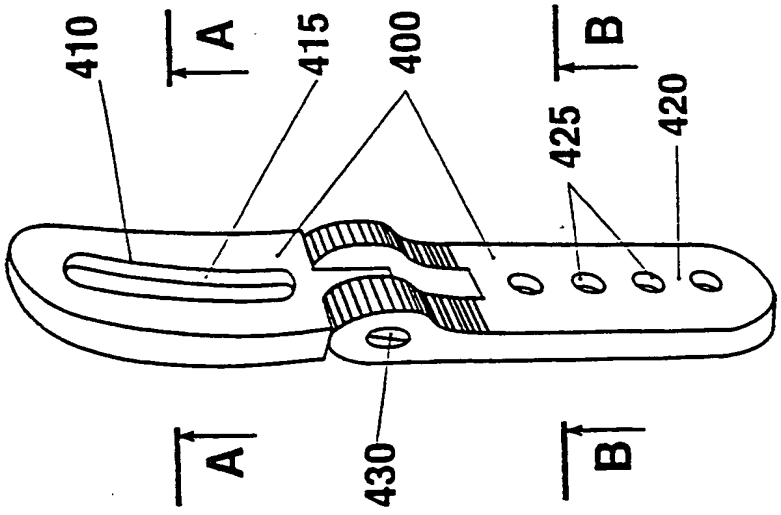

FIG.2(d)

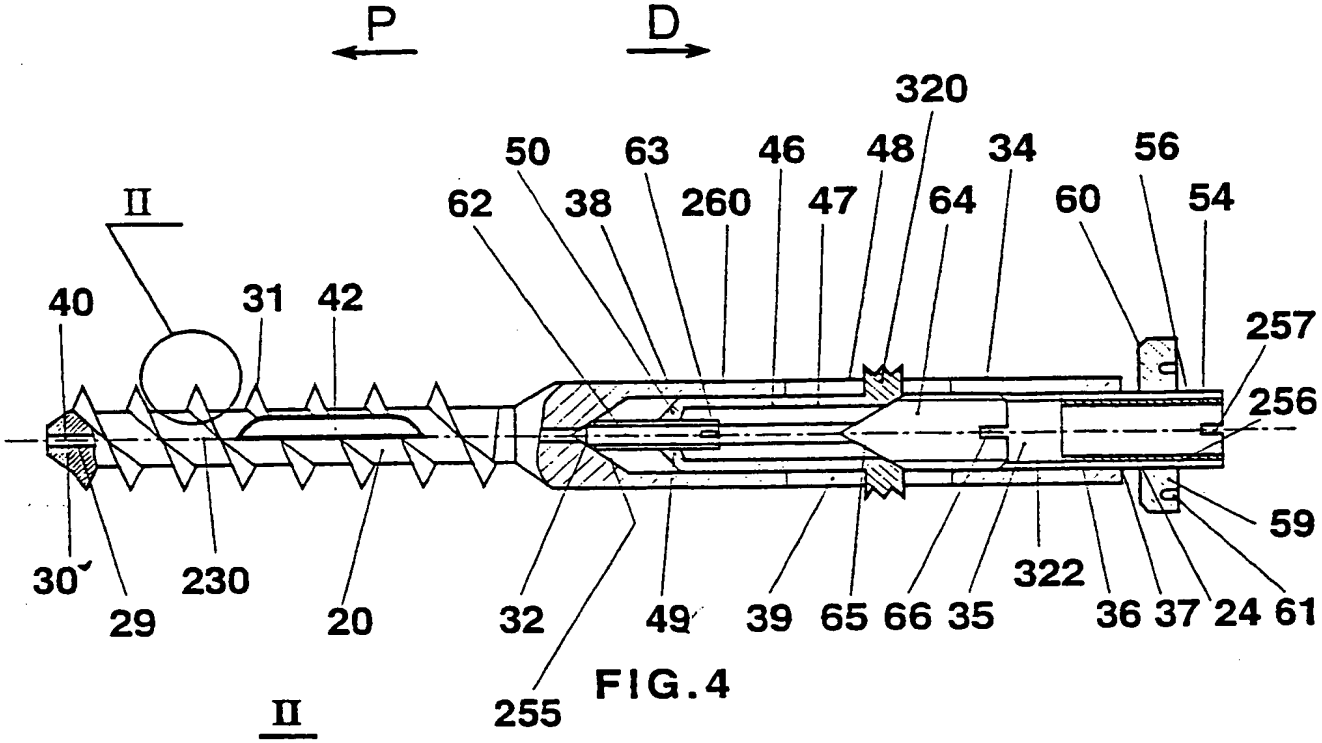

FIG.4

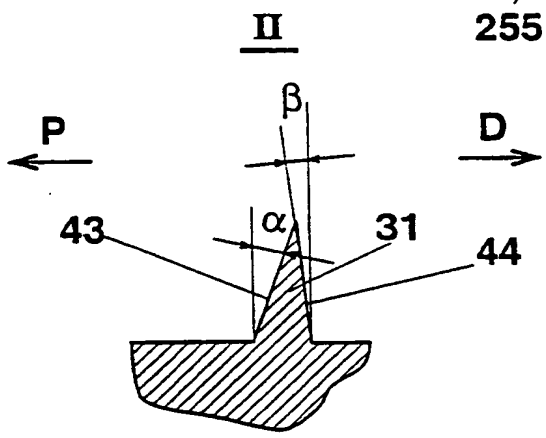

FIG.5

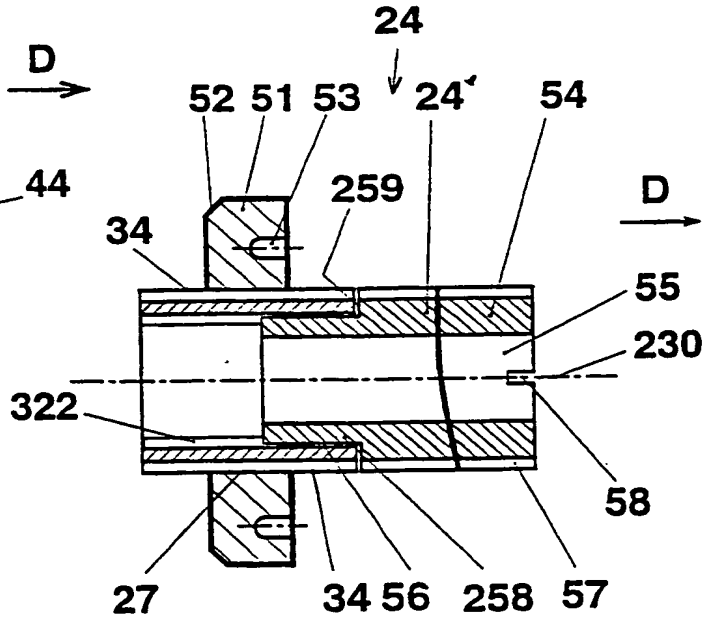

FIG.6

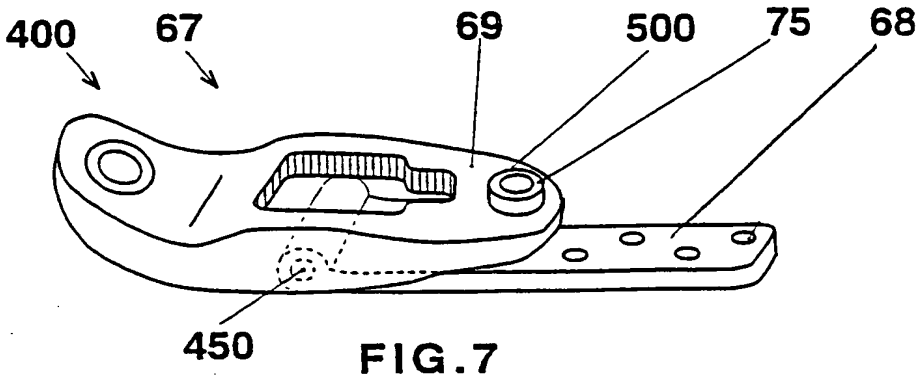

FIG.7

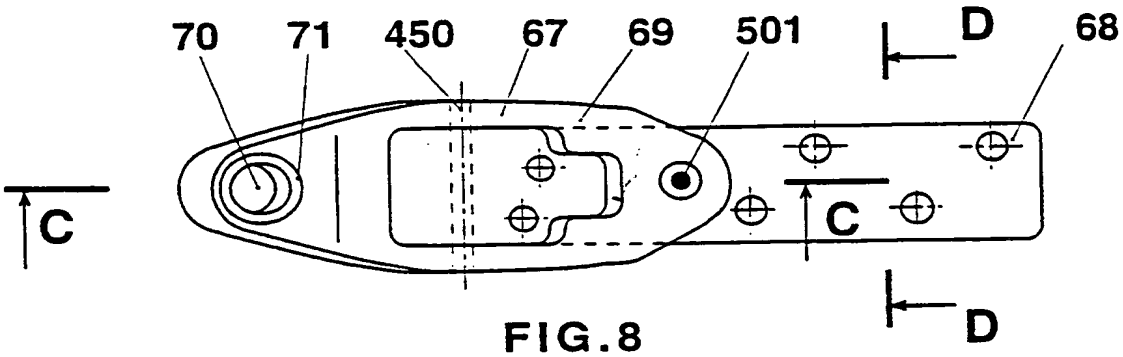

FIG.8

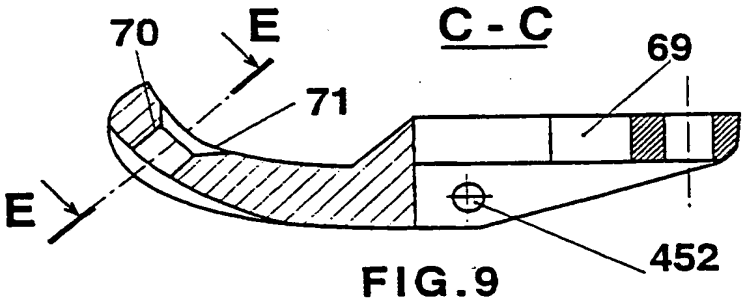

FIG.9

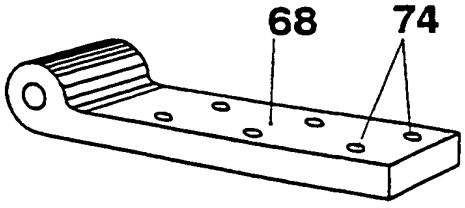

FIG.10

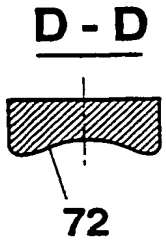

FIG.11

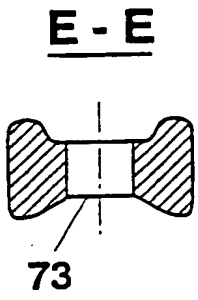

FIG.12

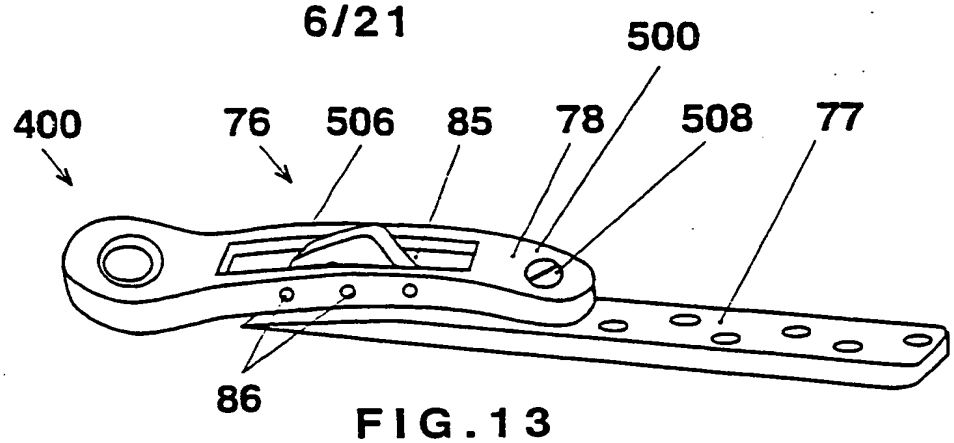

FIG.13

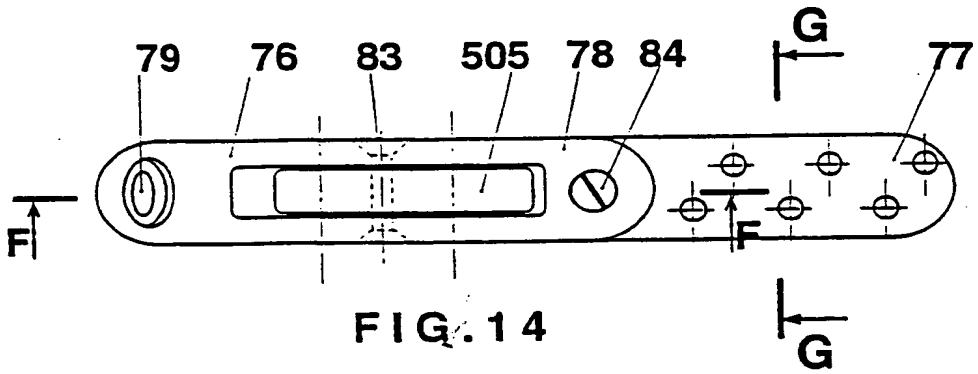

FIG.14

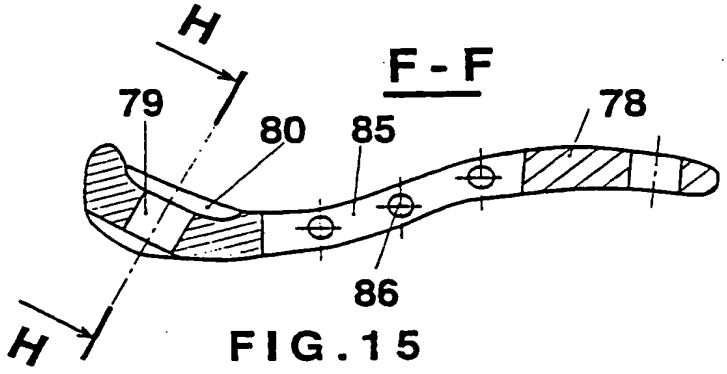

FIG.15

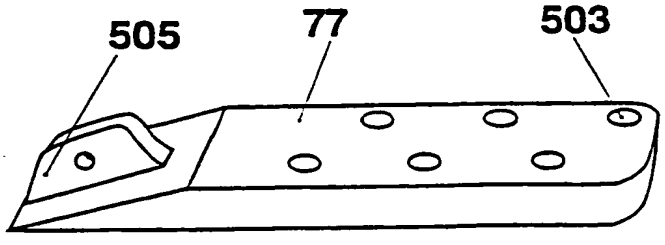

FIG.16

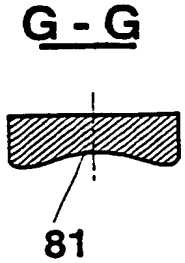

FIG.17

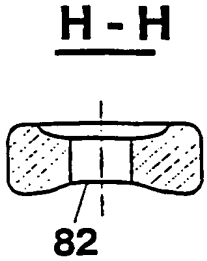

FIG.18

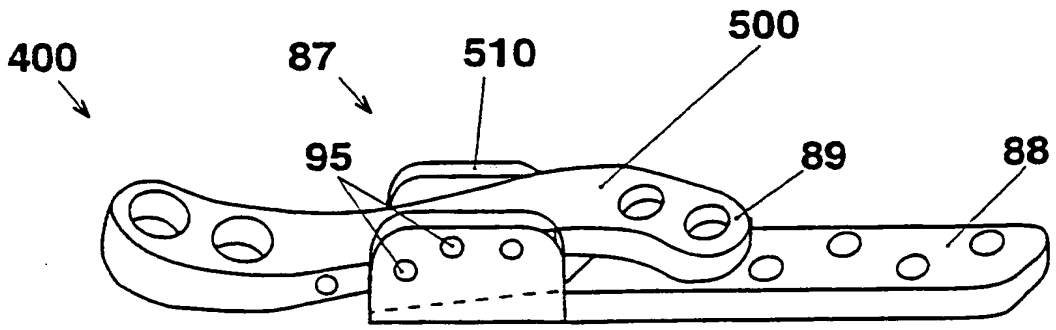

FIG.19

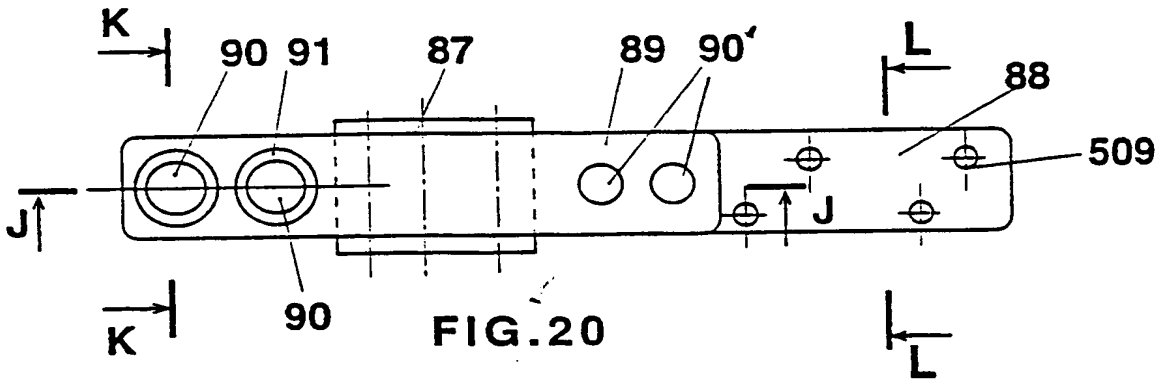

FIG.20

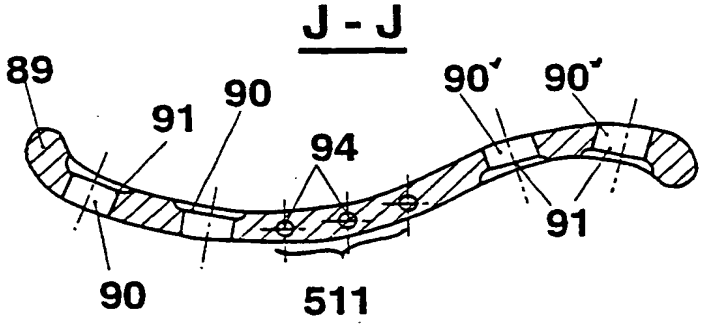

FIG.21

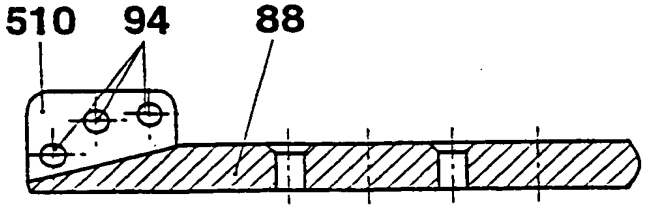

FIG.22

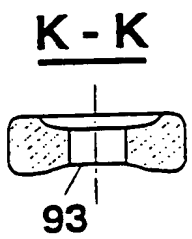

FIG.23

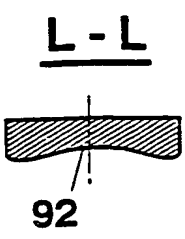

FIG.24

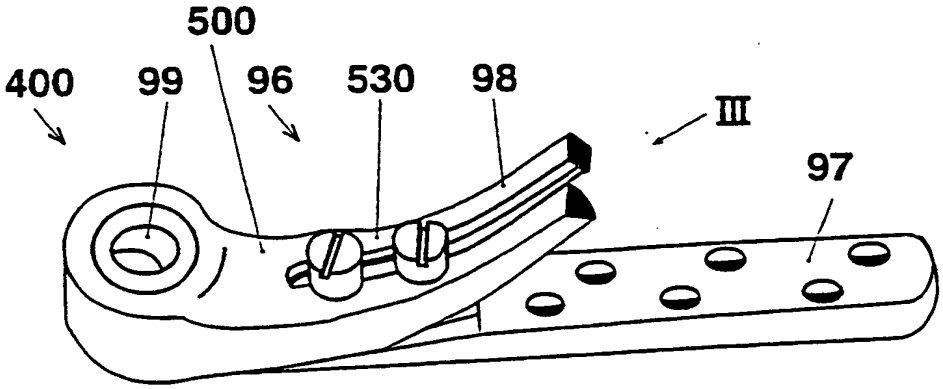

FIG.25

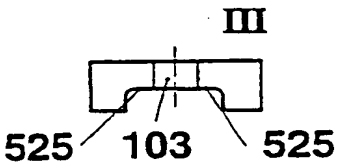

FIG.26

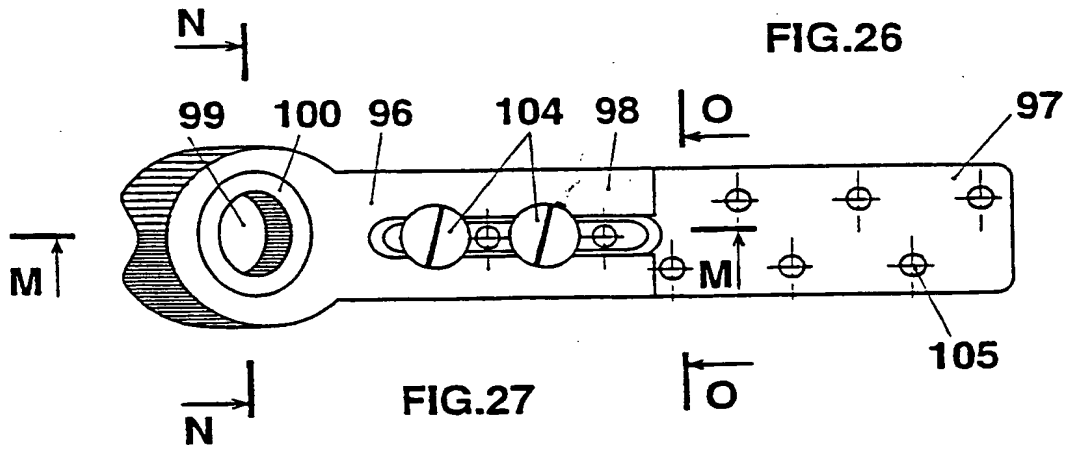

FIG.27

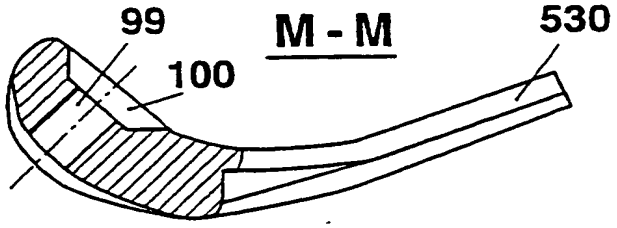

FIG.28

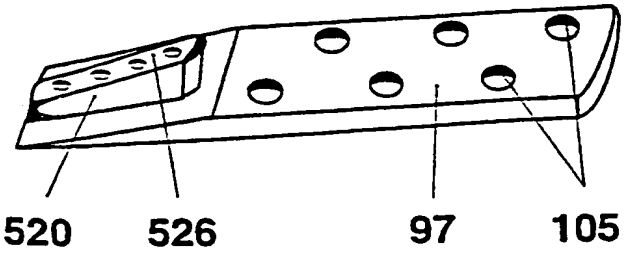

FIG.29

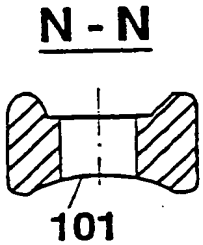

FIG.30

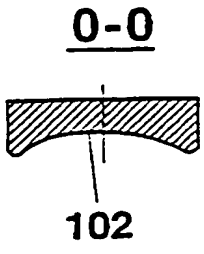

FIG.31

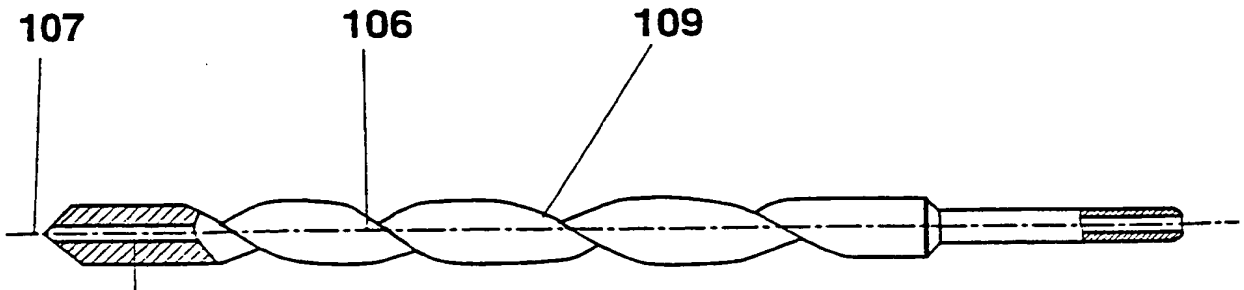

FIG.32

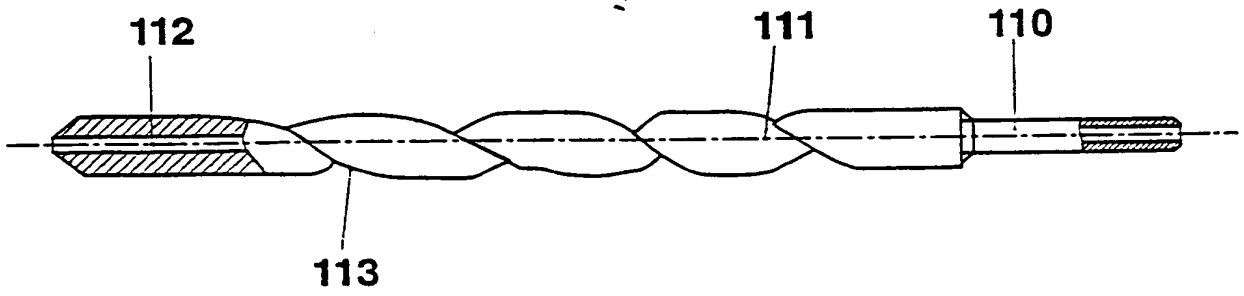

FIG.33

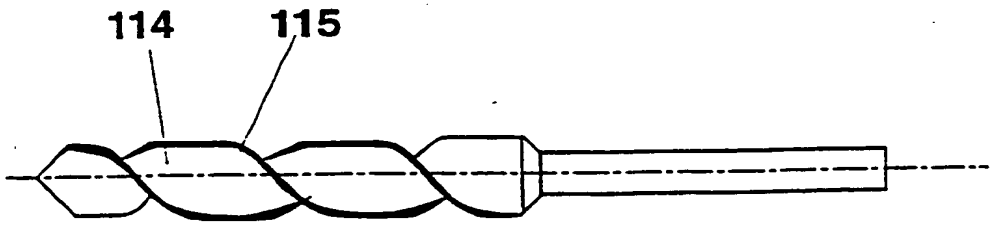

FIG.34

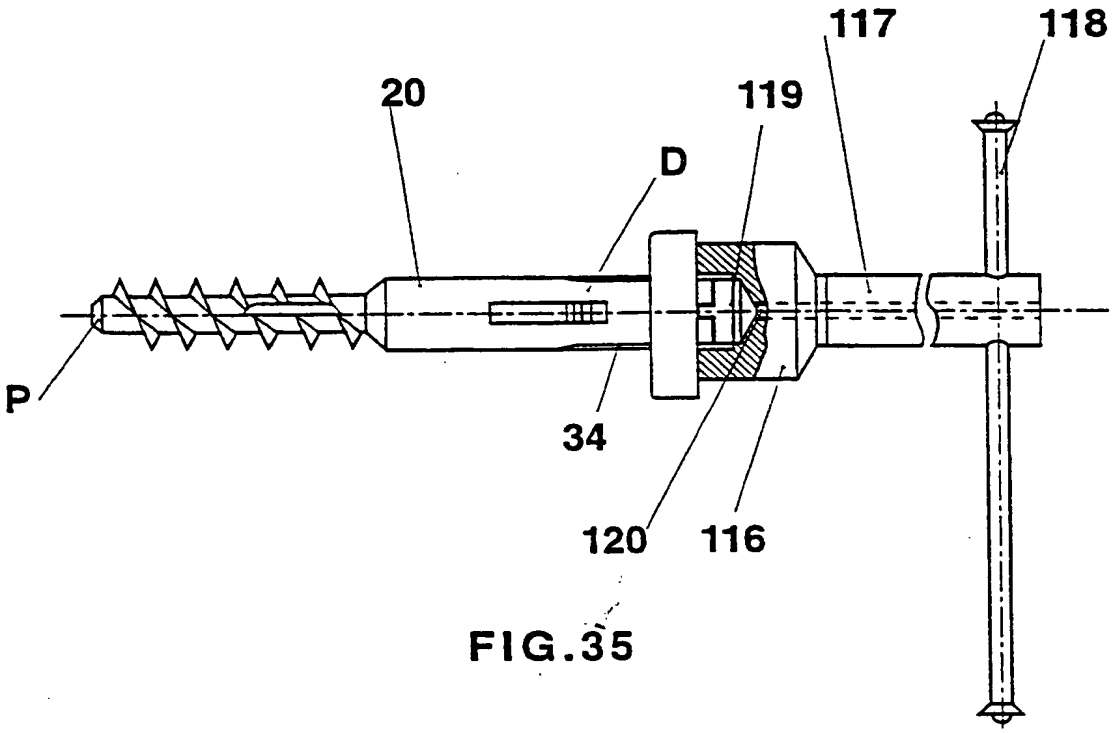

FIG.35

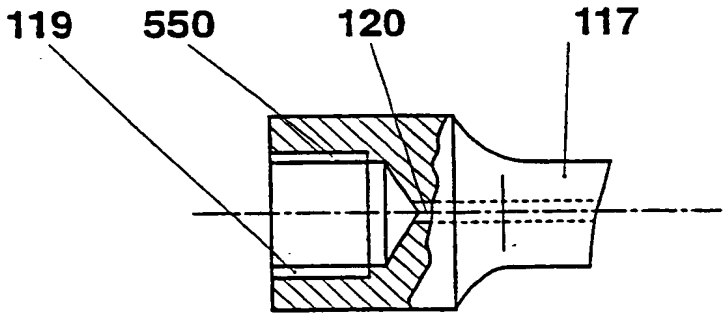

FIG.36

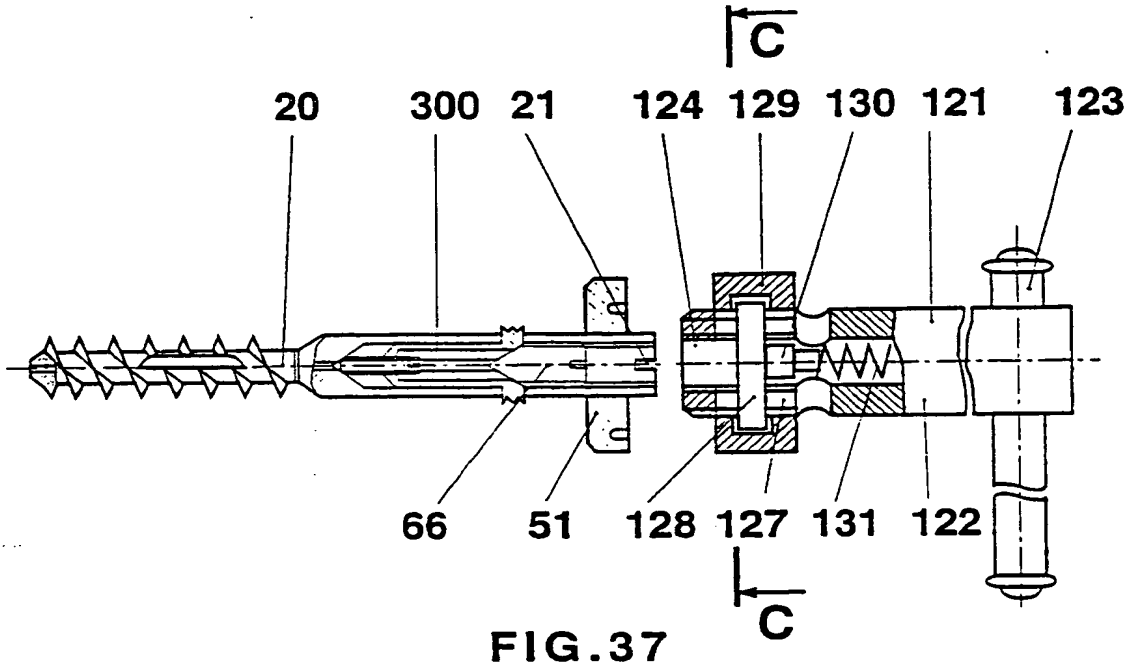

FIG.37

C - C

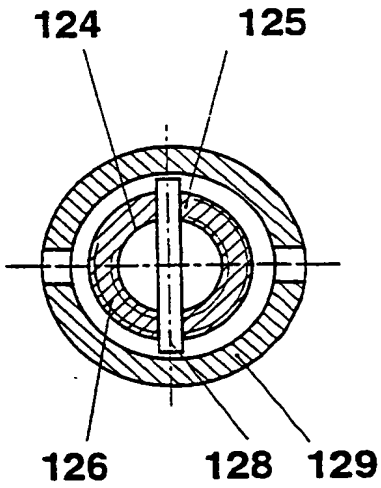

FIG.38

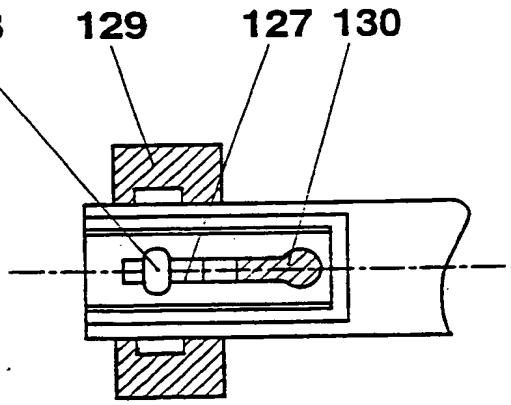

FIG.39

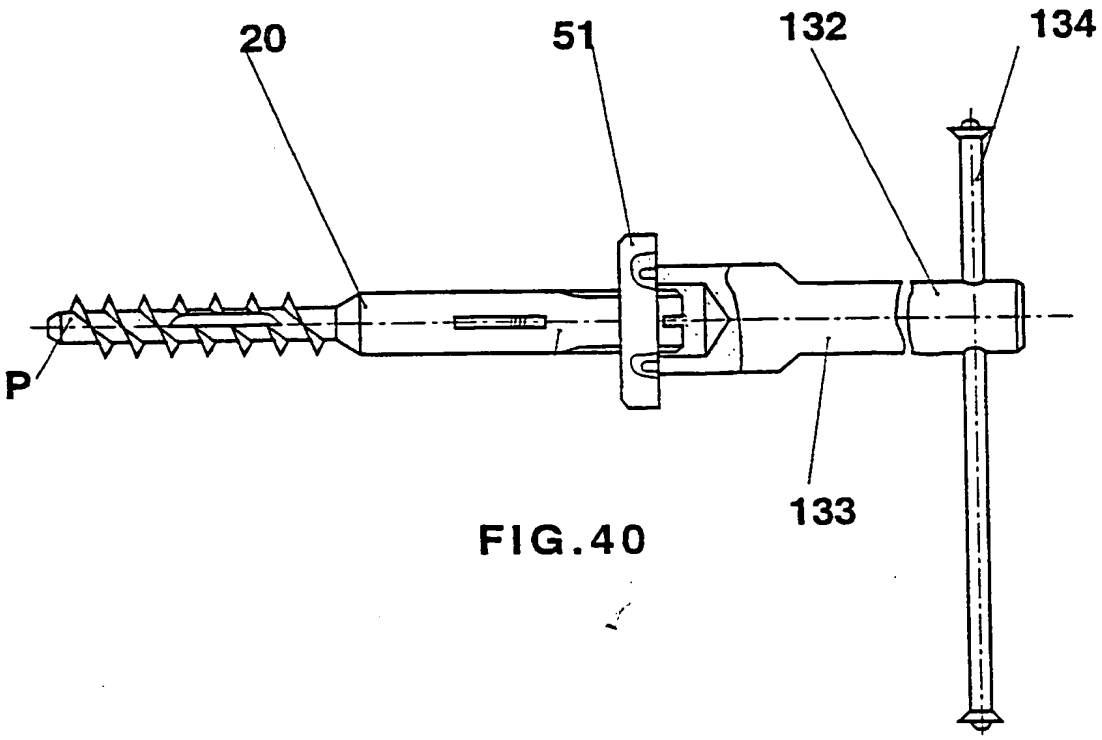

FIG.40

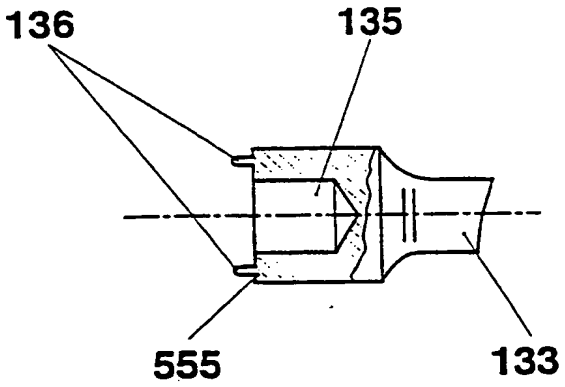

FIG.41

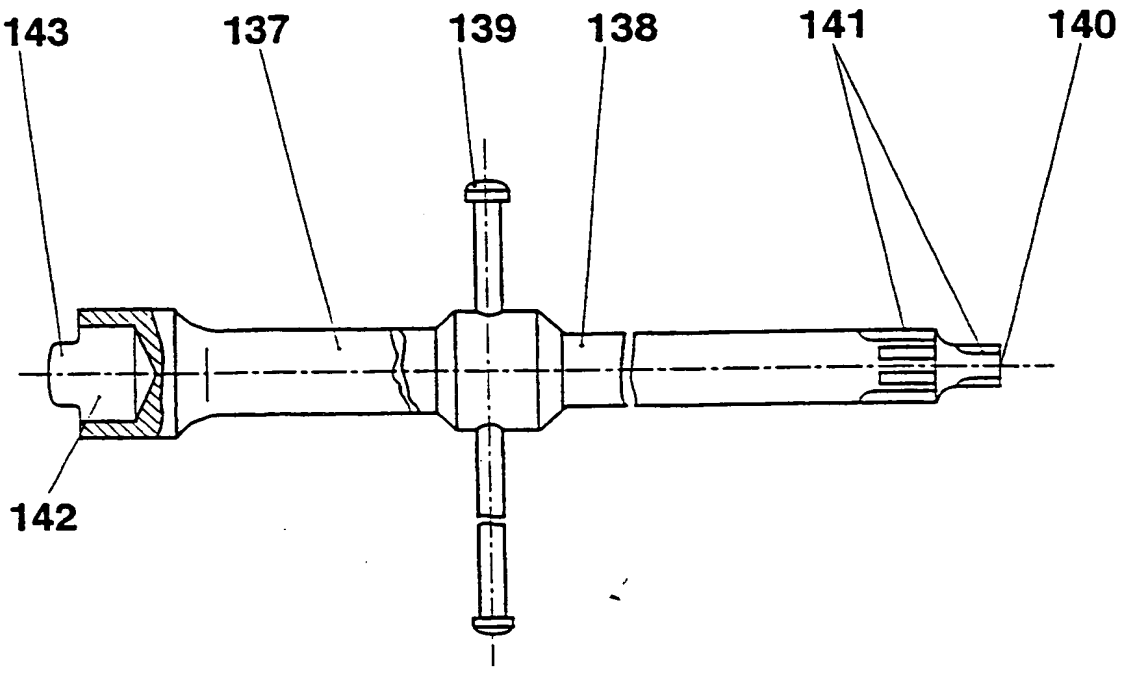

FIG.42

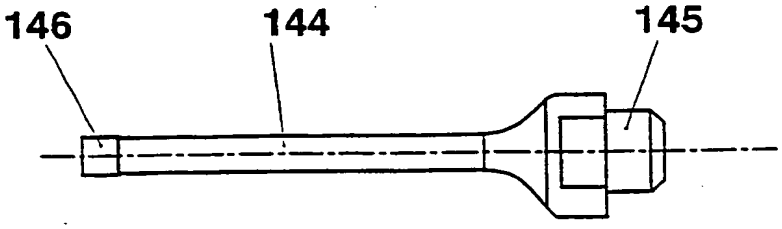

FIG.43

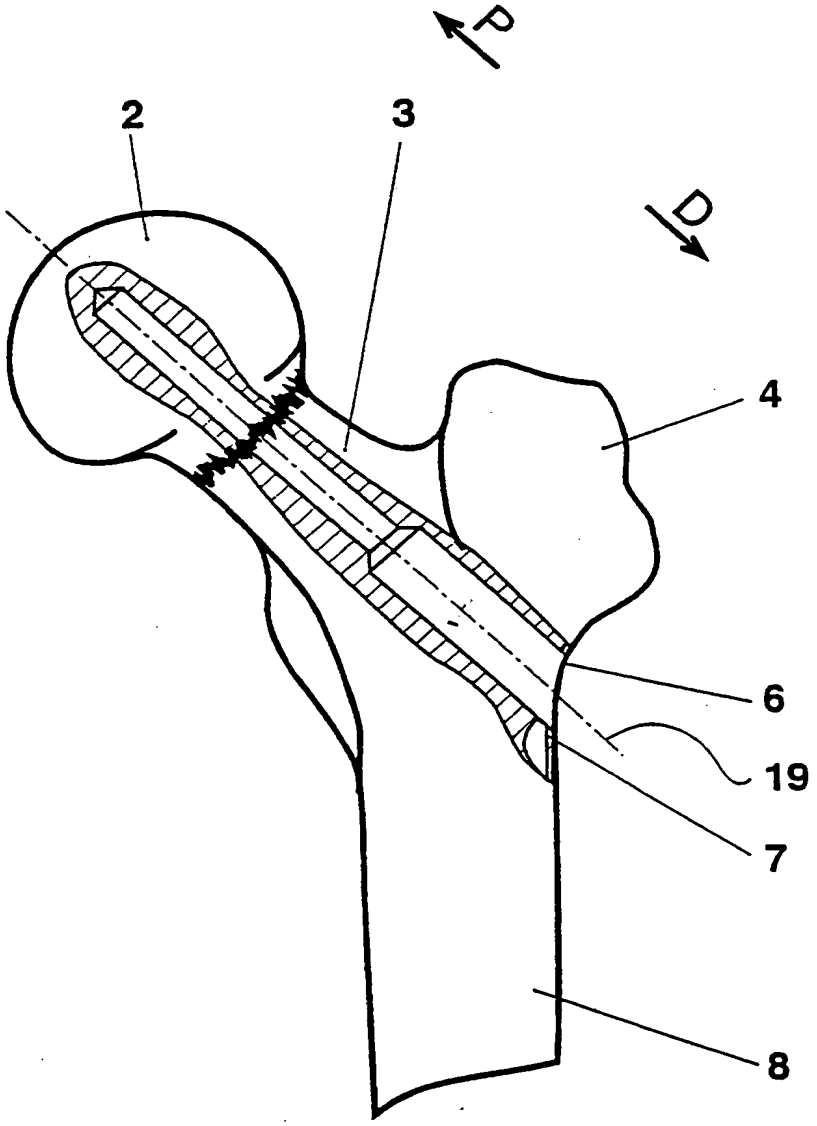

FIG.44

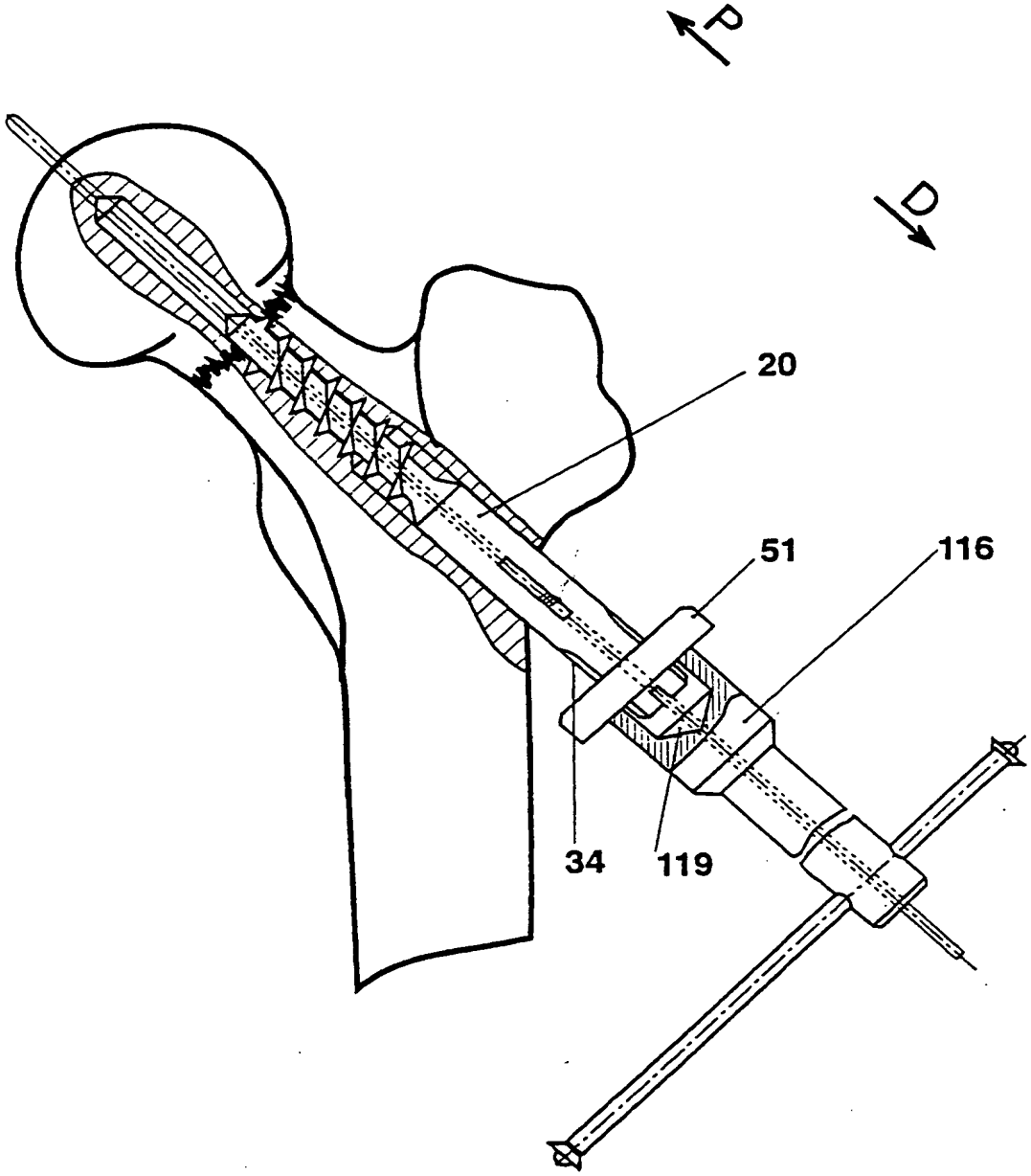

FIG.45

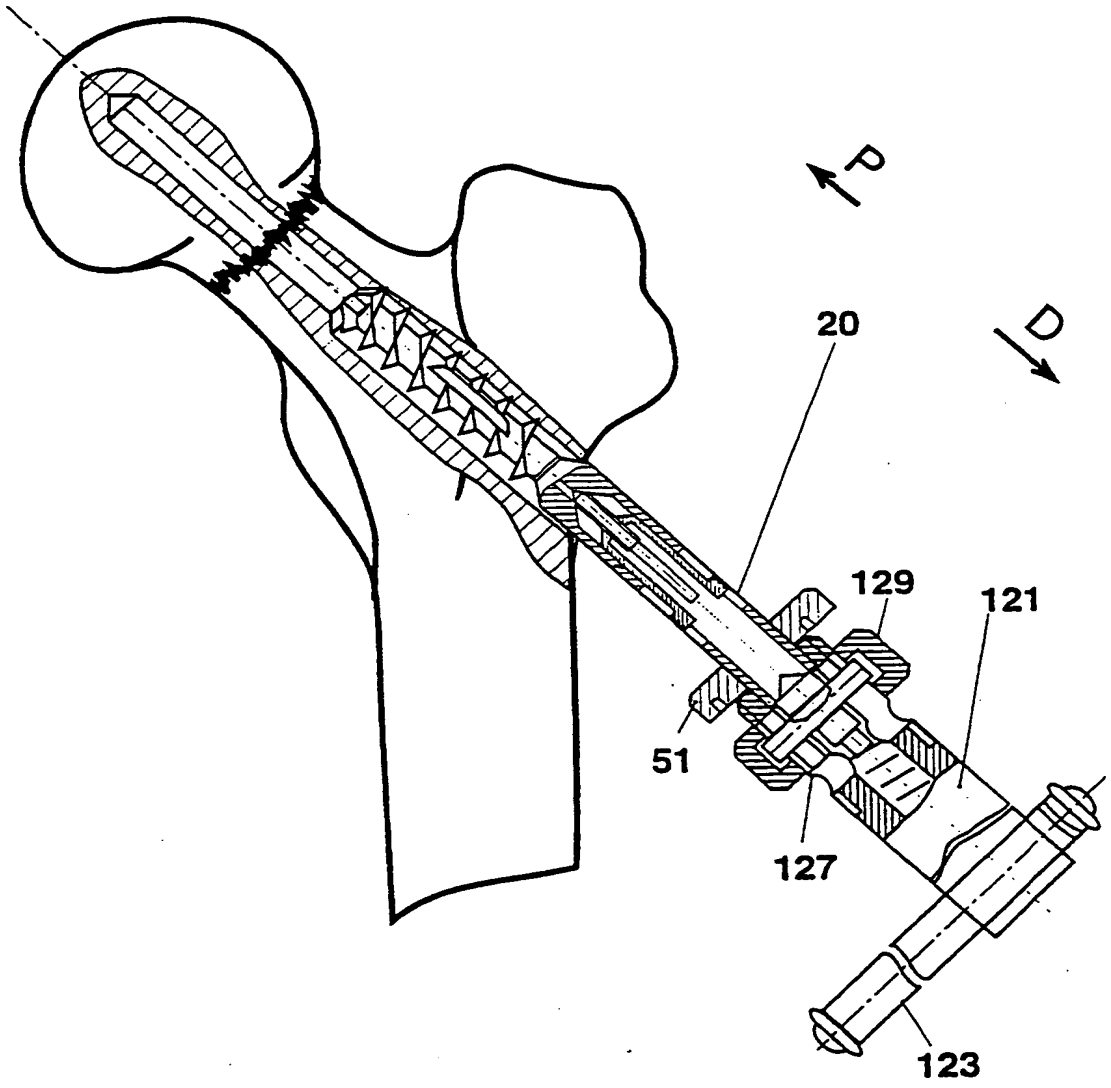

FIG.46

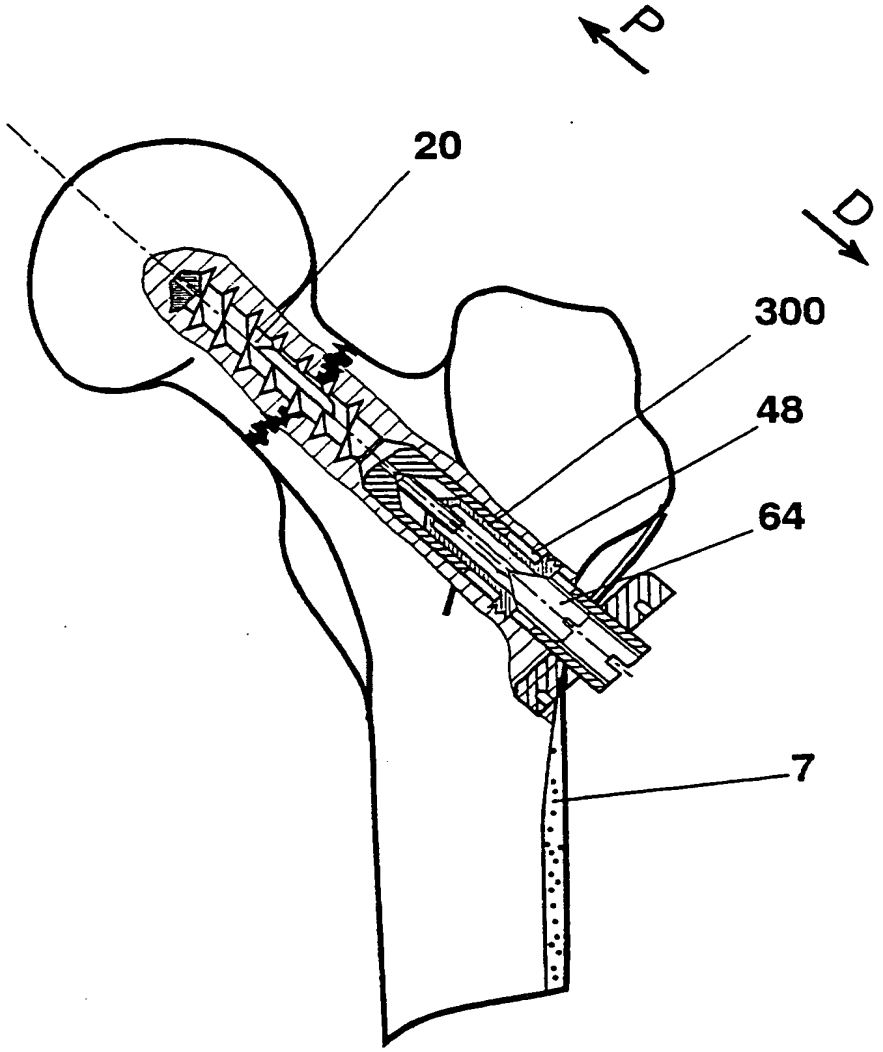

FIG.47

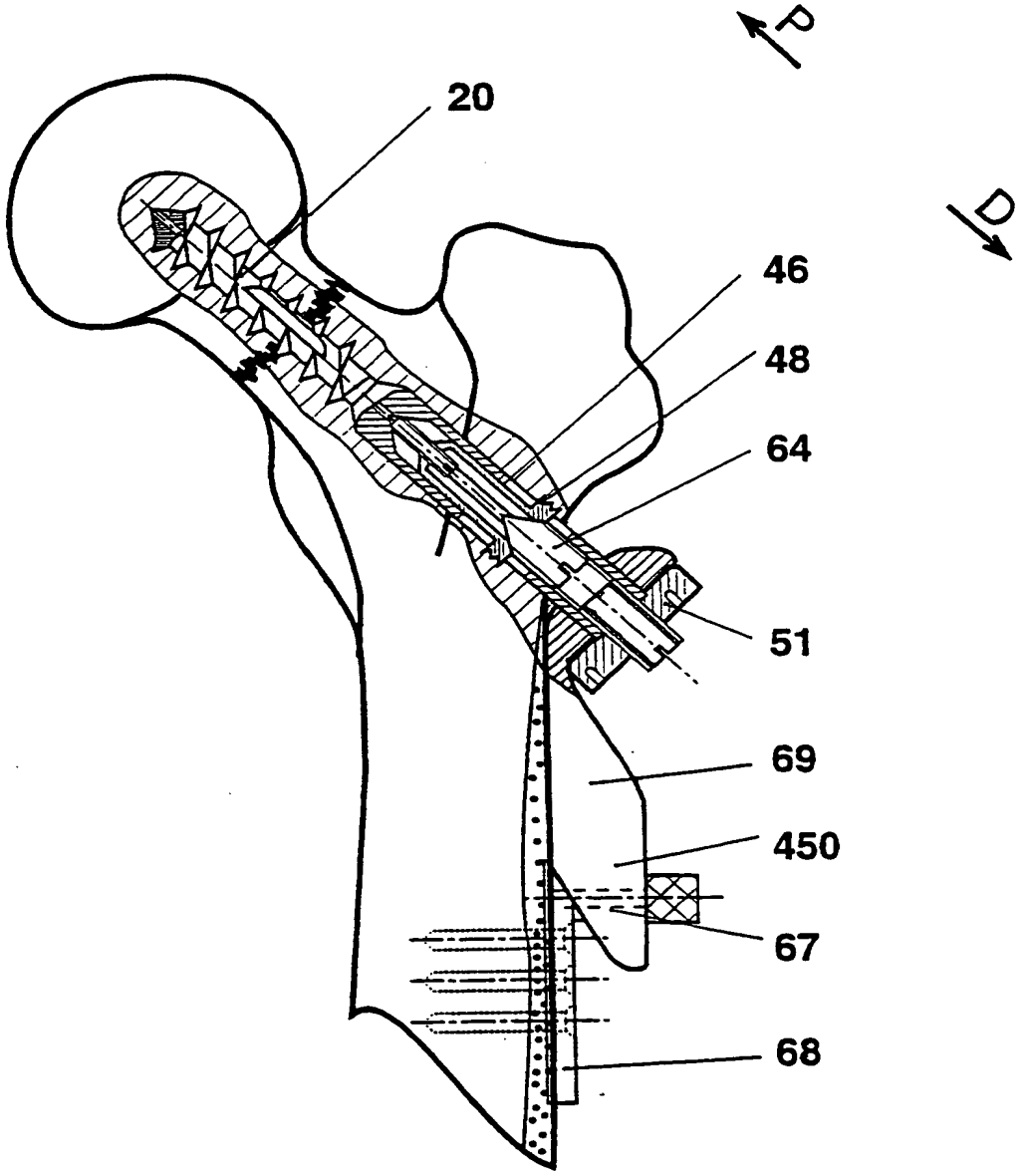

FIG.48

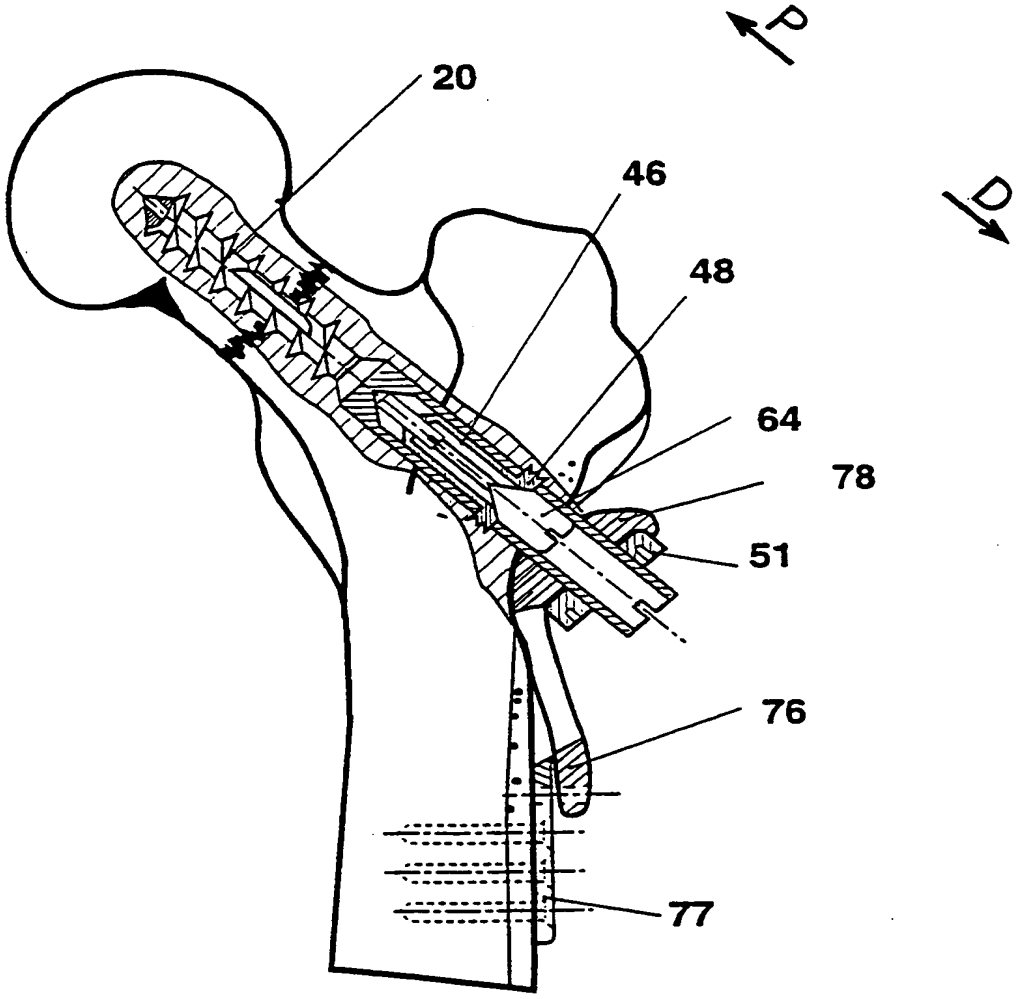

FIG.49

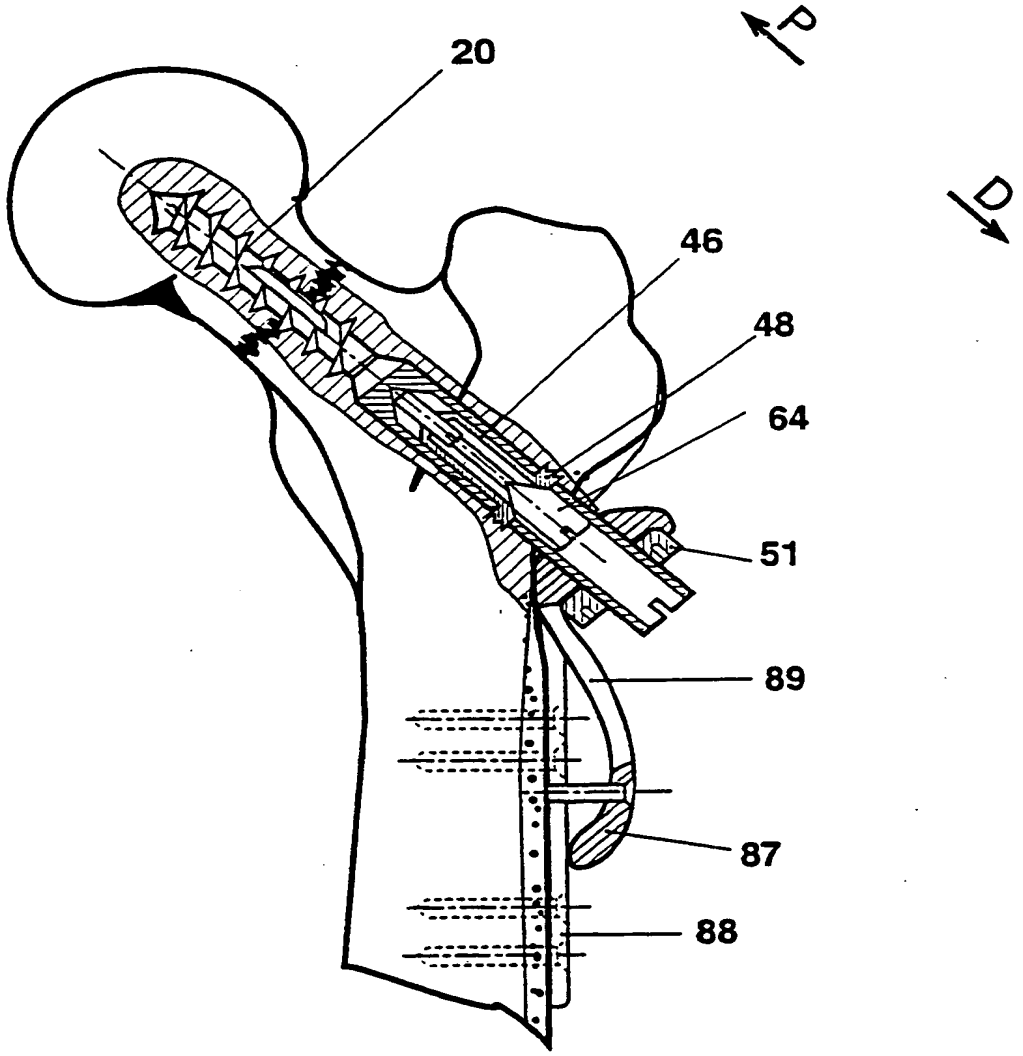

FIG.50

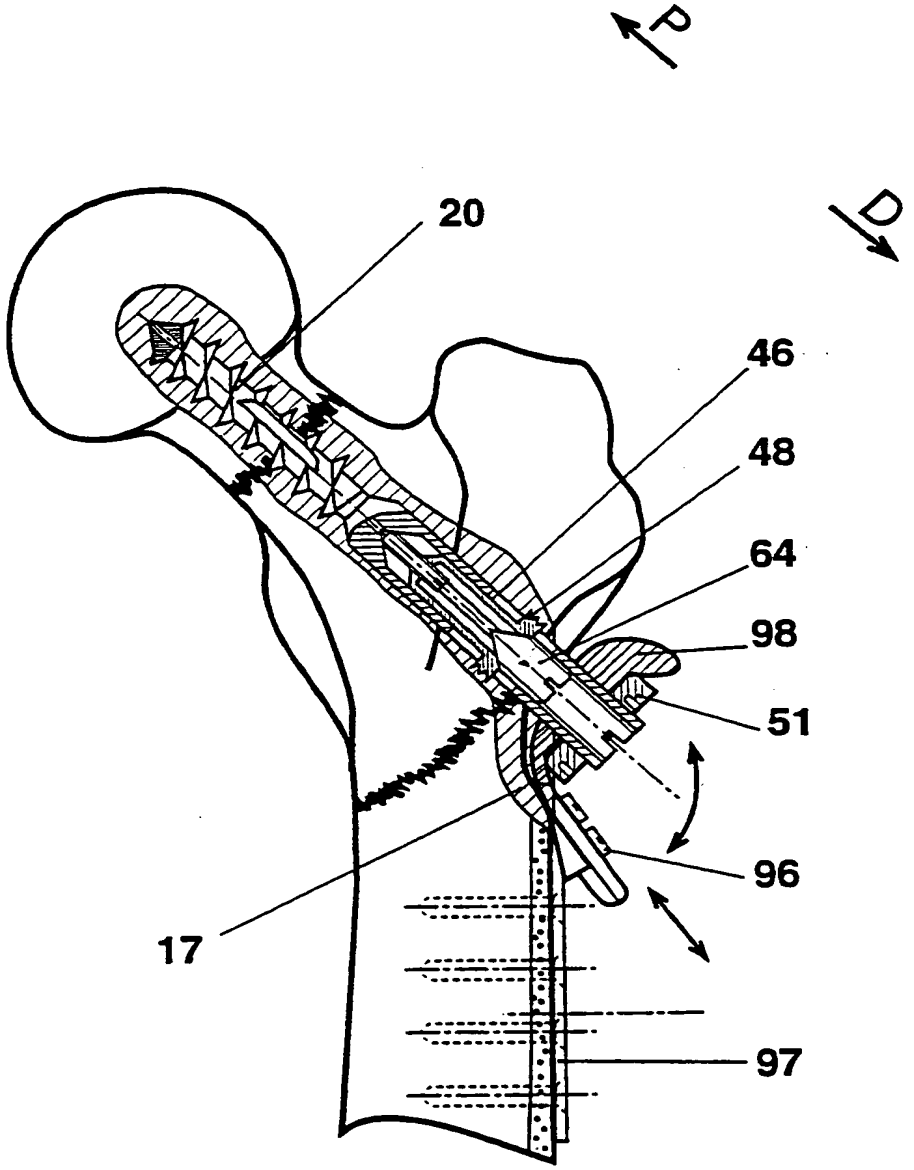

FIG.51

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 00/00269

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/74 A61B17/86 A61B17/72 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02105 A (BRAMLET DALE G) 22 January 1998 (1998-01-22) page 13, line 27 -page 14, line 11 page 15, line 6 - line 21 figures 2,5,6	1,2,4,5, 7,10,12, 14,15, 25,36,58
A	CH 475 754 A (PAUL KLEUSER CHIRURGISCHE INSTRUMENTE UND APPARATE) 31 July 1969 (1969-07-31) column 2, line 17 - line 33; figure 1	1,2,4,5, 7,21,36, 58
A	EP 0 636 346 A (SANTANGELO MASSIMO) 1 February 1995 (1995-02-01) the whole document	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 September 2000	26/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ducreau, F

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 437 674 A (KOVACS ERIC ET AL) 1 August 1995 (1995-08-01) column 3, line 26 - line 65; figure 1	1,2,4,5, 7,58
A	US 4 432 358 A (FIXEL IRVING E) 21 February 1984 (1984-02-21) figures 1,2	1-5,8
A	US 4 236 512 A (AGINSKY JACOB) 2 December 1980 (1980-12-02) claim 1; figure 1	1,21,25, 58
A	FR 2 653 660 A (HECHARD PATRICK) 3 May 1991 (1991-05-03) claim 1; figure 5	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 00/00269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802105 A	22-01-1998	US 5976139 A	02-11-1999
		AU 3662597 A	09-02-1998
		EP 0925038 A	30-06-1999
CH 475754 A	31-07-1969	NONE	
EP 0636346 A	01-02-1995	JP 7067897 A	14-03-1995
		US 5534004 A	09-07-1996
		US 5759184 A	02-06-1998
US 5437674 A	01-08-1995	FR 2695026 A	04-03-1994
		AT 182063 T	15-07-1999
		AU 670456 B	18-07-1996
		AU 4963893 A	15-03-1994
		BR 9305618 A	02-01-1996
		CA 2122017 A	03-03-1994
		DE 69325642 D	19-08-1999
		DE 69325642 T	06-04-2000
		EP 0609425 A	10-08-1994
		ES 2136666 T	01-12-1999
		WO 9404086 A	03-03-1994
		HU 67894 A,B	29-05-1995
		JP 7500520 T	19-01-1995
		NO 941487 A	22-04-1994
US 4432358 A	21-02-1984	NONE	
US 4236512 A	02-12-1980	NONE	
FR 2653660 A	03-05-1991	FR 2626169 A	28-07-1989